IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

FERRING PHARMACEUTICALS INC., REBIOTIX INC. Plaintiffs, v. FINCH THERAPEUTICS GROUP, INC., FINCH THERAPEUTICS, INC., and FINCH THERAPEUTICS HOLDINGS, LLC. Defendants.	C.A. No. 21-1694-RGA
FINCH THERAPEUTICS GROUP, INC., FINCH THERAPEUTICS, INC., FINCH THERAPEUTICS HOLDINGS, LLC, and REGENTS OF THE UNIVERSITY OF MINNESOTA Counterclaim-Plaintiffs/Reply Defendants, v. FERRING PHARMACEUTICALS INC., and REBIOTIX, INC. Counterclaim-Defendants/Reply Plaintiffs.	

JOINT CLAIM CONSTRUCTION BRIEF

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I. INTRODUCTION

A. Finch and UMN

Finch, powered by its patented inventions including those at issue in this case, is an industry-leading pioneer actively developing novel drug therapies to treat serious health conditions using new technologies concerning helpful bacterial that live inside us. A healthy human gut flourishes with life, including many beneficial bacteria, called the "microbiota." In the elderly, or when a patient's gut undergoes radical change—*e.g.*, due to high dose antibiotics—the composition of the microbiota changes, allowing potentially deadly bacteria such as *Clostridium difficile* to take hold. This life-altering infection causes debilitating diarrhea, and can cause perforation of the colon and death.

Before Finch's inventions, a handful of desperate doctors treated *C. difficile* infections by transplanting stool of a healthy donor into patients using rudimentary techniques that could not be scaled for use in widely-available drug therapies. But the challenges of soliciting one-off fecal donations—which, along with living, microscopic bacteria (fecal flora), also contains rough, macroscopic material (*e.g.*, fiber) that presents issues with respect to treatment—prevented widespread acceptance of "fecal microbiota transplant" (FMT) therapies. Recognizing these problems, Dr. Borody, as well as pioneering scientists at the University of Minnesota led by Drs. Sadowsky and Khoruts, invented new technologies that revolutionized the field of bacteriotherapy. For example, Dr. Borody developed new techniques for processing donor stool to separate microscopic bacteria from the macroscopic "rough particulate matter" in the stool, while allowing substantially the entire microbiota to remain; as another example, the UMN scientists developed additional techniques to render stool suitable for drug delivery, extracting and preparing the feces to achieve the right balance of bacterial classes and nonliving material,

improving effectiveness and engraftment. And in general, the inventors realized a centralized "stool bank" would help avoid problems and that standardization was key.

Rebiotix was born not from its own innovation, but from watching the development of these inventions from the sidelines. Lee Jones, Rebiotix's founder, learned about the inventions directly from the UMN inventors shortly before founding Rebiotix. When Drs. Khoruts and Sadowsky found a different partner to support their research and product development, Ms. Jones left UMN to found Rebiotix, less than six months later, with no prior experience or formal training in microbiome therapeutics. It is unsurprising, then, that Rebiotix's RBX2660 product practices the patents. Rebiotix unilaterally chose to file this declaratory judgment action, without any pre-warning or engagement with Finch, acknowledging the importance of Finch's patents and Rebiotix's infringement thereof.

Now, having no answer to its infringement, Rebiotix proposes constructions unhinged from the claims and other intrinsic evidence, improperly limiting the claims to preferred embodiments, or excluding embodiments altogether. And when all else fails, Rebiotix implausibly claims that easily understood phrases are indefinite. Finch's constructions, in contrast, are rooted in the intrinsic evidence and the plain and ordinary meanings of the claim language, consistent with the intrinsic evidence and the context of the inventors' contributions.

B. Plaintiffs

Ferring Pharmaceuticals Inc. ("Ferring") is a research-driven, specialty biopharmaceutical group committed to helping people around the world build families and live better lives. Founded in 1950, privately-owned Ferring is a leader in reproductive medicine and maternal health, and in specialty areas within gastroenterology and urology.

In April 2018, Ferring acquired Rebiotix Inc. ("Rebiotix," collectively with Ferring, "Plaintiffs"), a late-stage clinical microbiome company focused on harnessing the power of the

human microbiome to revolutionize the treatment of challenging diseases. Rebiotix's portfolio included RBX2660 (trade named REBYOTA), which was being studied for its potential to reduce recurrence of *C. difficile* infection ("CDI") after antibiotic treatment. REBYOTA is a microbiota suspension derived from human stool and is administered via enema.

In contrast, Finch does not have (and is not close to having) an approved product. Finch did not develop the alleged inventions claimed in the patents in suit. Instead, it acquired patents from Thomas Borody (the Borody Patents) and licensed patents from the University of Minnesota (the UMN patents). Finch then drafted claims directed to enema fecal microbiota transfer ("FMT") products (even though its FMT product in development is an oral capsule) in an attempt to cover Ferring's REBYOTA.

Recognizing this, Plaintiffs brought this declaratory judgment action against Finch to ensure that, if approved, REBYOTA could be launched as the first FDA-approved FMT therapy in the United States. The technology claimed in the Borody patents (now owned by Finch) is old. Fecal transplants were done in ancient times, and the first modern fecal transplant was completed in the 1950's. The claims of the Borody patents are not novel—they simply cover compositions occurring in nature with minimal processing steps using conventional techniques. Dr. Borody's allegedly "new techniques for processing donor stool to separate microscopic bacteria from the macroscopic 'rough particulate matter' in the stool, while allowing the substantially entire microbiota to remain" (*supra* at 1) are nothing more than practicing the prior art.

After answering, Finch amended its Counterclaims to add UMN as a party and to assert the UMN patents. Like the Borody patents, the UMN patents similarly are directed to methods of using compositions that, if Finch's constructions are correct, are naturally occurring. However, Counterclaimants assert that "the UMN scientists developed additional techniques to render stool

suitable for drug delivery, extracting and preparing the feces to achieve the right balance of bacterial classes and nonliving material." (*Id.*) If true, then the UMN patents are achieving the "right balance" by active selection of the bacteria to include in the product, as Plaintiffs contend.

Contrary to Counterclaimants' assertion, Plaintiffs' proposed constructions are not "unhinged from the claims and other intrinsic evidence," (*supra* at 2), rather, they are specifically tied to the disclosures (or lack thereof) in the Borody patents and the UMN patents. This is in stark contrast to Counterclaimants' proposed constructions, which either do not resolve the dispute between the parties (for those terms where Counterclaimants have simply proposed the "plain and ordinary meaning") or seek to take words in isolation and out of the context of the patents. Neither do Plaintiffs' proposed constructions "improperly limit[] the claims to preferred embodiments," (*supra* at 2), as Counterclaimants contend. Indeed, the Borody patents do not even disclose a single preferred embodiment. Further, the Federal Circuit has long recognized that some embodiments are often disclosed and not claimed.

Plaintiffs submit that their proposed constructions are the proper constructions, considering the intrinsic evidence, including the claims themselves, the specifications, and the prosecution history—and those constructions are further bolstered by the extrinsic evidence.

II. REPRESENTATIVE CLAIMS

A. Borody Patents

1. '406 Patent claim 4

4. A filtered and homogenized stool composition comprising the *substantially entire microbiota* of a stool and an added antioxidant, wherein said stool composition is *free of rough particulate matter* of said stool.

2. '413 Patent claim 1

1. A method comprising:
receiving a stool sample from a healthy donor at a central location, wherein the donor has been prescreened for infectious agents;
placing the stool sample within a stool collection device; mixing the stool sample with a liquid to form a mixture, wherein the liquid comprises a buffer and a cryoprotectant;
homogenizing and filtering the mixture to separate fiber from bacteria and produce a filtrate comprising a *substantially entire microbiota* of the stool sample

3. '107 Patent claims 1, 2, and 12

1. A method comprising:
receiving at a central location a non-frozen stool sample from a donor, wherein the stool sample is within a stool collection device;
testing the stool sample for pathogens;
mixing the stool sample with a cryoprotectant to form a mixture; and
homogenizing the mixture to produce a composition comprising viable bacteria from the stool sample.

2. The method of claim 1, wherein the method further comprises filtering the composition to produce a filtrate.

12. The method of claim 2, wherein *the filtering separates bacteria from rough particulate matter*.

4. '702 Patent claims 11 and 13

11. An enema delivery system comprising a bag, flexible tubing, and a pharmaceutical composition within the bag, wherein the pharmaceutical composition is formulated for enema delivery directly from the bag via the flexible tubing, wherein the

pharmaceutical composition comprises saline, polyethylene glycol and the *substantially entire microbiota* of a stool sample *separated from rough particulate matter* of the stool sample, wherein the bag comprises an oxygen-resistant material, and wherein the pharmaceutical composition is in an *amount effective* for treating recurrence of *C. difficile* infection.

13. The enema product of claim 11, wherein the *substantially entire microbiota is free of rough particulate matter* of the stool sample.

5. '309 Patent claims 1 and 12

1. An enema delivery system configured for transporting to a remote facility, the enema delivery system comprising a container, flexible tubing, and a pharmaceutical composition within the container, wherein the pharmaceutical composition is formulated for enema delivery from the container via the flexible tubing, wherein the pharmaceutical composition comprises saline, a cryoprotectant and a preparation of viable uncultured non-pathogenic fecal bacteria, wherein the fecal bacteria are from a stool of a human donor, wherein the container is sealed, wherein the pharmaceutical composition is *free of rough particulate matter*, and wherein the pharmaceutical composition is in an amount effective for treating recurrence of *C. difficile* infection.

12. An enema product configured for transporting to a remote facility, the enema product comprising flexible tubing, a sealed bag, and a pharmaceutical composition within the bag, wherein the pharmaceutical composition is formulated for enema delivery from the bag, wherein the pharmaceutical composition comprises saline, a cryoprotectant and a suspension of viable non-pathogenic fecal bacteria, wherein the fecal bacteria are from a stool of a human donor, wherein the fecal bacteria are *separated from rough particulate matter* and are not cultured, and wherein the pharmaceutical composition is in an amount effective for treating recurrence of *C. difficile* infection.

B. UMN Patents

1. ’914 Patent claim 9

A method of decreasing the relative abundance of one or more members of the phylum Proteobacteria in a patient in need thereof, the method comprising:
administering to said patient an *effective amount* of a pharmaceutical composition comprising a *human fecal microbe preparation* comprising a pharmaceutically acceptable carrier and a *human fecal extract* comprising a human fecal donor's intestinal microbiota comprising *at least 6 different classes of bacteria selected from the group consisting of Actinobacteria, Bacteroidia, Bacilli, Clostridia, Erysipelotrichi, Alphaproteobacteria, Betaproteobacteria, Gammaproteo-bacteria, Mollicutes, and Verrucomicrobiae*, wherein said *human fecal extract* comprises particles of non-living material and particles of biological material, and said *human fecal extract* comprises no particle having a size of greater than 0.5 mm,
wherein the relative abundance of one or more members of the phylum Proteobacteria is reduced by at least 10% following administration of said pharmaceutical composition.

2. ’011 Patent claim 1

A method of increasing fecal micro biota diversity in a human patient in need thereof and having a Clostridium difficile infection (CDI), the method comprising:
administering to said patient an *effective amount* of a pharmaceutical composition comprising a *human fecal microbe preparation* comprising a pharmaceutically acceptable carrier and a *human fecal extract* comprising a human fecal donor's intestinal microbiota comprising *at least 6 different classes of bacteria selected from the group consisting of Actinobacteria, Bacteroidia, Bacilli, Clostridia, Erysipelotrichi, Alphaproteobacteria, Betaproteobacteria, Gammaproteo-bacteria, Mollicutes, and Verrucomicrobiae*, wherein said *human fecal extract* comprises particles of nonliving material and particles of biological material, and said *human fecal extract* comprises no particle having a size of greater than 0.5 mm,
wherein the administering increases the diversity of said patient's fecal microbiota compared to before said administering, and wherein said patient's fecal microbiota after said administering cluster more closely to the microbiota of the donor's feces using Yue and Clayton's Theta Index.

3. ’012 Patent claim 1

A method of increasing the relative abundance of one or more members of the phylum Firmicutes in a patient in need thereof, the method comprising:
administering to said patient an *effective amount* of a pharmaceutical composition comprising a *human fecal microbe preparation* comprising a pharmaceutically acceptable carrier and a *human fecal extract* comprising a human fecal donor's intestinal microbiota comprising *at least 6 different classes of bacteria selected from the group consisting of Actinobacteria, Bacteroidia, Bacilli, Clostridia, Erysipelotrichi, Alphaproteobacteria, Betaproteobacteria, Gammaproteo-bacteria, Mollicutes, and Verrucomicrobiae*,
wherein said *human fecal extract* comprises particles of nonliving material and particles of biological material, and said *human fecal extract* comprises no particle having a size of greater than 0.5 mm,
wherein the administering increases the relative abundance of total members of the phylum Firmicutes by at least 20% compared to before said administering.

III. AGREED-UPON CONSTRUCTIONS

The parties have agreed to the following proposed constructions:

Term	Claims	Agreed-upon Construction
"no particle having a size of greater than 0.5 mm"	'011 patent: claim 1 '012 patent: claim 1	"no particle greater than 0.5 mm as shown by sieving"
"amount effective"	'702 patent: claims 1, 11 '309 patent: claims 1, 12	"a sufficient amount to provide the desired effect"

IV. DISPUTED CONSTRUCTIONS IN THE BORODY PATENTS

A. "rough particulate matter"

Term	Plaintiffs' Proposed Construction	Finch's Proposed Construction
'406 patent: claim 4 '107 patent: claims 12, 25 '702 patent: claims 1, 11, 12 '309 patent: claims 1, 12	Indefinite	"irregular, macroscopic non-fecal floral material"

1. Finch's opening position

Contrary to Rebiotix's assertions, the term "rough particulate matter" is not indefinite, but rather—in accordance with the well-known words used in that phrase and as confirmed throughout the specification—refers to "irregular, macroscopic non-fecal floral material." First, the claim language and specification make clear that "rough particulate matter" is "non-fecal floral material," *i.e.*, not the bacteria. For example, every claim that includes this phrase explicitly distinguishes between rough particulate matter, on the one hand, and the living, fecal floral "bacteria," on the other. *See, e.g.,* '309 patent claim 1 ("wherein the pharmaceutical composition comprises…a preparation of viable uncultured non-pathogenic fecal bacteria…wherein the pharmaceutical composition is free of rough particulate matter"). There is nothing indefinite about that distinction, which is clearly delineated in the claim language itself, and directly supports the "non-fecal floral material" aspect of Finch's construction.

Second, rough particulate matter is "macroscopic" in size: as the claim language and specification confirm, "rough particulate matter" is distinct from microscopic fiber/nonliving material and microscopic bacteria that are present in stool. According to the specification, a key step in the preparation of the patented compositions is to remove "non-bacterial" "rough

particulate matter," leaving the microscopic parts of the stool; *i.e.*, "microscopic fiber/nonliving matter," which "is then separated from the bacteria":

> In alternative embodiments, to separate the non-bacterial components and produce a stable product that can be frozen or lyophilized and have a long shelf life, the stool can be homogenized and filtered from rough particulate matter. In alternative embodiments, the microscopic fiber/nonliving matter is then separated from the bacteria.

Id. at 21:18-25. According to the specification, the purpose of that step—to "homogenize[] and filter[]" the stool "from rough particulate matter"—is to "remove large particles of matter." *Id*. at 20:39-41 ("In alternative embodiments, once cleared of infective agents, it is homogenized and filtered to remove large particles of matter."); *see also* 7:41-45 ("the fecal flora is separated from rough particulate matter . . . by: homogenizing, centrifuging and/or filtering a rough particulate matter or a non-floral matter of the fecal material"); 9:41-48 (same), 11:55-67 (same). Once again, there is nothing indefinite about this distinction: as repeatedly confirmed throughout the claims and specification, the removal of the rough particulate matter is distinct from the follow-on processing of what remains; *i.e.,* the microscopic non-living matter and bacteria. *Id.*; *see also* 23:1-7 ("In alternative embodiments, a crude collected stool is filtered and/or homogenized, and then its bacterial cells are separated (e.g., from the "crud" which contains the fiber) . . . .").

The dependent claims make this distinction as well: dependent claim 12 of the '107 patent refers to filtering that "separates bacteria from rough particulate matter." '107 patent at claim 12. By contrast, claim 11 refers to filtering that "separates bacteria from microscopic fiber." *Id*. at claim 11; *Versa Corp. v. Ag-Bag Int'l Ltd.*, 392 F.3d 1325, 1330 (Fed. Cir. 2004) ("The difference in meaning and scope between claims is presumed to be significant to the extent that the absence of such difference in meaning and scope would make a claim superfluous.").

These are basic undisputed facts that are repeated throughout the intrinsic evidence, confirming that Finch's proposed construction is correctly directed to the macroscopic, non-living portion of the donor stool.

Third, there is also no question that "rough" particles are "irregular" in shape, as proposed in Finch's construction. This is a well-understood meaning of "rough." Ex. 53, Concise Oxford English Dictionary 11th Ed. (2008) (defining "rough" to mean "having an uneven or irregular surface; not smooth or level."); Ex. 54, Webster's New World College Dictionary, 4th Ed. (2010) ("not smooth or level; having bumps, projections, etc."). The specification confirms this aspect of Finch's construction, repeatedly stating that rough particulate matter is separated from stool by, for example, using homogenization, centrifugation, or filtering ('309 patent, 7:39-48; 9:40-48), all processes that by definition leave a composition more uniform in form, removing "irregular" matter. Lastly, the specification consistently refers to non-fecal floral matter as "material," just as in Finch's proposed construction. *See e.g., id*. at 5:27, 5:35, 5:52-53, 6:4-5, 8:5, 10:28.

Contrary to Rebiotix's assertions, rough particulate matter is not indefinite. *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014). As discussed above, the specification repeatedly confirms precisely what rough particulate matter is—*i.e.,* the rough (or irregular) macroscopic, non-living material in stool. '309 patent at 7:41-45, 9:41-48, 11:55-67; 20:39-41; 21:18-25, 23:2-3. It is unsurprising, therefore, that when the Examiner[1] of the Borody patents expressly considered whether this term is indefinite, it was determined that it is not. *See* Ex. 38 at JA0621 ("Applicant has replaced said term with 'free of rough particulate matter of the stool

[1] The same examiner analyzed all of the Borody Patents at issue.

sample,' which is considered definite so the rejection has been withdrawn."); *see also* Ex. 35 at JA0603-5; Ex. 36 at JA0609; Ex. 37 at JA0611-3,614. That alone should preclude a finding that Rebiotix has established indefiniteness by clear and convincing evidence. *Nature Simulation Sys. Inc. v. Autodesk Inc.*, 23 F.4th 1334, 1342-43 (Fed. Cir. 2022) (holding no indefiniteness, where applicant "in consultation with the examiner, amended" the claim to add the term in dispute and examiner "withdrew the indefiniteness rejection" thereafter) (quoting *Tinnus Enters., LLC v. Telebrands Corp.*, 733 F. App'x. 1011, 1020 (Fed. Cir. 2018)). The Court should reject Rebiotix's bid at invalidating this easily-understood term, and adopt Finch's construction.

2. Plaintiffs' answering position

The Borody patents are verbose, confusing, lack clarity, and at times, internally inconsistent. Nevertheless it is the specification that informs the meaning of the terms used in the claim. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1315 (Fed. Cir. 2005) ("The claims . . . are part of 'a fully integrated written instrument,'" and "'must be read in view of the specification, of which they are a part.'" (quoting *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 978-79 (Fed Cir. 1995)). Indeed, "the specification is always highly relevant to the claim construction analysis. Usually, it is dispositive . . . ." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996).

Contrary to Counterclaimants' assertion, the Borody patents do not confirm that the term "rough particulate matter" has a well-known, well-understood, and well-defined meaning (*Supra* at 10.) At best, the Borody patents only hint at a subjective description of what is—or is not—"rough particulate matter," and that subjective description is further confused because the Borody patents use ambiguous and inconsistent wording when allegedly referring to "rough particulate matter."

The use of "rough particulate matter" in the claims makes clear why the term would be indefinite to a person of ordinary skill in the art ("POSA"). *See Nautilus*, 572 U.S. at 901. Here, the term "rough particulate matter" consistently appears in the claims in phrases that require quantification, such as "free of rough particulate matter," or "separated from rough particulate matter." As discussed below, these phrases require at least some quantification. But one cannot consistently quantify a purely subjective term. Here, "rough particulate matter" is akin to saying a person is "tall" or "short"—individuals have different perceptions of what those subjective terms mean. There are individuals that everyone would agree are tall, just as there are individuals that everyone would agree are short, but there is a broad range of individuals in the middle where the "tall" or "short" determination amounts to an individual judgment call by the observer. To quantify, it would be necessary to have a limit; for example, people over 6.5' are tall and people under 4.5' are short.

The same is true with the term "rough particulate matter" in the Borody patents. The Borody patents provide no quantitative properties of "rough particulate matter," such as a size limitation (which are routine in the pharmaceutical industry (Declaration of Dr. Richard Alan Johnson, dated November 10, 2022 ("Johnson Decl.") at ¶ 39), and without such a disclosure in the specification, there will be particles that all POSAs would agree are "rough particulate matter" and particles that all POSAs would agree are not "rough particulate matter." But there will also be a wide range of particles that fall somewhere in between, and where reasonable POSAs may make different determinations. That is the hallmark of indefiniteness. *Media Rts. Techs., Inc. v. Capital One Fin. Corp.*, 800 F.3d 1366, 1371 (Fed. Cir. 2015) (A term "is indefinite if its language 'might mean several different things and no informed or confident

choice is available among the contending definitions.'" (quoting *Nautilus*, 572 U.S. at 910 n. 8 (2014)).

Counterclaimants attempt to address this issue by asserting that the term has a definite meaning— "irregular, macroscopic non-fecal floral material." Counterclaimants' construction is still wholly subjective and adds no clarity. In fact, it creates more ambiguity. First, the Borody patents do not use the terms "irregular" and "macroscopic." Counterclaimants assert that "irregular" is a synonym for "rough" and both mean, essentially, not smooth or having an irregular surface. Although Counterclaimants do not provide a definition of "macroscopic" it generally is understood to mean "capable of being seen with the naked eye." (Johnson Decl. at ¶ 37; *see also* Ex. 57 at JA0804; Ex. 58 at JA0808; Ex. 59 at JA0813 and Ex. 60 at JA0818.) Both terms are subjective and introduce additional ambiguity. For example, if "rough" means "irregular" then "rough particulate matter" would exclude smooth undigested food, such as a kernel of corn. This cannot be the case because the Borody Patents make clear that undigested food is part of the "crud" to be removed from the bacteria. (Ex. 1 at 2:7-21, 23:1-7.) Similarly, an "irregular" particle is one that has no line of symmetry (for example, because of bumps or protrusions). (Johnson Decl. at ¶ 36; *see also* Ex. 57 at JA0803; Ex. 58 at JA0807; and Ex. 60 at JA0817.) This again excludes much of the "non-living" material in stool, including, for example, corn and most beans and seeds, have at least one line of symmetry and thus are not "irregular."

Similarly, the term "macroscopic" is subjective and provides no additional clarity. There is no dispute that aside from the rare outlier, most bacteria (and particles approaching the size of bacteria) cannot be seen with the naked eye. These are not "rough particulate matter." (*See, e.g.,* Ex. 1 at 21:21-25 (noting that "microscopic fiber" can be filtered such that it is removed "coming down to the size of the bacterium").) Similarly, corn or larger seeds can easily be seen by the

naked eye. But there is a range where particulates may or may not be "macroscopic." The determination can be influenced by a range of human and environmental factors; what is macroscopic in a particular situation may not be macroscopic in another. (*See* Johnson Decl. at ¶¶ 37-38.) For example, generally, humans can discern particles down to approximately 50 to 100 microns (the average human hair being approximately 50-70 microns)—0.05 to 0.1 mm. (*Id.* at ¶ 38.) But visualizing those particles is dependent on lighting and the medium in which they appear. (*See id.* at ¶¶ 37-38.) A dark particle on a white background or suspended in a clear liquid under a bright light can be visible and still discernable at a much smaller size than a translucent particle or a particle against a similarly colored background and in dimmer lighting. (*See id.* at ¶ 38.) Such vagaries mean that one POSA could determine there is "rough particulate matter" while another may determine the exact opposite for the same composition, even setting aside differences in a POSA's ability to see or differentiate colors.

Further, the term "non-fecal floral material" creates more confusion. The plain meaning of the term does not, as Counterclaimants assert, mean "not the bacteria." (Opening at 4-5.) Rather, taking the terms at face value, it refers to bacterial flora that are not from the feces. This is not the same as non-living material in the feces or "not the bacteria" (and is, in fact, essentially the opposite). Confusingly, the common specification of the Borody Patents also refers to "non-fecal floral fecal material," which means bacteria that are both "non-fecal" and "fecal" at the same time. (*See, e.g.*, Ex. 1 at 9:58-67.) The common specification of the Borody patents also refers to non-bacterial material in the feces. (*See, e.g.*, at 7:39-48 (describing isolating fecal flora from "a non-floral matter of the fecal material"); *id.* at 11:55-67 (same); *see also id.* at 11:51-54 (referring to isolating the fecal flora from "fecal material"). Only this last description is consistent with the idea that the "rough particulate matter" is "not the bacteria" and is the

undigested food and other fibrous material in the feces. Thus, adopting Counterclaimants' proposed construction would require rewriting the claims and specification to change the meanings of the words "non-fecal floral material" to "non-floral matter of the fecal material", something this Court should not do. *Acceleration Bay LLC v. Activision Blizzard, Inc.*, 324 F. Supp. 3d 470, 478 (D. Del. 2018) (quoting *K-2 Corp. v. Salomon S.A.*, 191 F.3d 1356, 1364 (Fed. Cir. 1999) ("As a general matter, '[c]ourts do not rewrite claims; instead, [they] give effect to the terms chosen by the patentee.'")).

Finally, as discussed more fully below, Counterclaimants' citation to Exhibit 38 is inapposite to the meaning of the term "rough particulate matter." There, the examiner held the term "substantially devoid of fiber" indefinite because "substantially devoid" was not quantifiable. Applicant changed the term to "free of rough particulate matter," which the examiner found definite because the term meant "without." (*See, infra,* §IV.B.2.)

Accordingly, the term "rough particulate matter" standing alone or under Counterclaimants' construction, fails to provide the metes and bounds of what is claimed, chiefly because nothing in the common specification of the Borody patents or prosecution history provides a quantitative measure, such as a size limitation, of what constitutes "rough particulate matter." Had the common specification provided any consistently quantifiable way to determine what is, and is not, "rough particulate matter" the term would be definite. It does not, and thus it is left to the POSA to determine what size and shape of particulates qualify as "rough particulate matter" and as such the term is indefinite. *Media Rts.*, 800 F.3d at 1371.

3. Finch's reply position

The patents repeatedly confirm throughout the claims and specification that the removal of the rough particulate matter—*i.e.,* the irregular, macroscopic non-fecal floral material—is distinct from the follow-on processing of what remains, *i.e.,* the microscopic non-living matter

and bacteria. *See, e.g.*, '309 patent at 20:39-41; 9:41-48, 11:55-67; 23:1-7. Rebiotix does not dispute this. This basic fact forms the basis for Finch's proposed construction.

Faced with these clear disclosures in the intrinsic record, Rebiotix asserts that the term is indefinite, primarily because it claims that "rough particular matter" appears in phrases that "require at least some quantification." Answer at 14. Not so. First, it is undisputed that rough particulate matter—which the patents repeatedly confirm is "macroscopic"—is "capable of being seen with the naked eye." November 10, 2022 Declaration of Dr. Richard Alan Johnson ("Johnson Decl.") ¶37. This is not a matter of degree like being "tall" or "short," *contra* Answer at 14: Either the particles can be seen with the naked eye (and are "macroscopic") or a microscope is necessary (and are not). Rebiotix's attempt to muddy the water fails. Lighting and the medium in which such particles appear—the two elements on which Rebiotix stakes part of its indefiniteness claim—are easily controlled and can be set such that a particle is visible to the naked eye or it is not.[2] Tellingly, Rebiotix's position conflicts with Federal Circuit law (let alone common sense), which confirms that "macroscopic" is an objective standard. *See Sonix Tech. Co. v. Publ'ns Int'l, Ltd.*, 844 F.3d 1370, 1378 (Fed. Cir. 2017) (finding "what can be seen by the normal human eye" to be "an objective baseline"). Regardless, whether the conditions are sufficient to allow for a particle to be seen with the naked eye or not is an ordinary matter of whether a claim term is met, and is far from sufficient to meet Rebiotix's high burden to show

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[2] For this unsupported conclusion, Rebiotix relies on its expert, who had no experience in the field of FMT at the time of the invention, did not review the literature in preparing his declaration, and was given the wrong legal standard for indefiniteness. Ex. 66 at 48:4-8; 54:17-55:16; 61:3-14. Even then, Dr. Johnson, who opined that the inventions were not "particularly complicated." Ex. 66 at 23:16-24:6. *See also id.* at 24:7-19. Dr. Johnson also does not dispute that the Borody patents distinguish rough particulate matter from microscopic non-living matter. Ex. 66 at 77:14-19.

indefiniteness. *Nautilus,* 572 U.S. at 901. Second, the Federal Circuit has rejected such arguments requiring numerical limits. *Guangdong Alison Hi-Tech Co. v. Int'l Trade Comm'n*, 936 F.3d 1353, 1362 (Fed. Cir. 2019); *Enzo Biochem, Inc. v. Applera Corp.*, 599 F.3d 1325, 1335 (Fed. Cir. 2010) ("the claims are not indefinite even though the construction of the term 'not interfering substantially' defines the term without reference to a precise numerical measurement").[3] Rebiotix's citation to *Media Rts.* is unavailing. That case found a means-plus-function limitation to be indefinite for lacking sufficient structure; "rough particulate matter" is not a means-plus-function limitation. *See Media Rts. Techs., Inc. v. Cap. One Fin. Corp.*, 800 F.3d 1366, 1374-75 (Fed. Cir. 2015).

Rebiotix's follow-on attempts to deride Finch's construction are likewise deficient. First, Rebiotix offers definitions of "irregular," but none for the term at issue, which is "rough particulate matter." Second, the term "irregular" is consistent with the claim language and the specification. *See, e.g.*, '309 patent, claim 1, 12 (requiring administration through flexible tubing); *id.* at 7:39-48; 9:40-48; 11:60-67. As confirmed throughout the specification, rough particulate matter consists of non-uniform particles, which are distinct from the uniform composition that remains after homogenization, centrifugation, or filtering. *See* '309 patent, 7:39-48; 9:40-48; 11:60-67. Contrary to Rebiotix's assertion, corn kernels are irregular as compared to the smooth product. This comports with a key step in the process—the removal of large particles of undigested food. *See* '309 patent, 20:38-41; Allegretti Decl. ¶32, 36. A POSA would readily envisage the material constituting "rough particulate matter." Allegretti Decl. ¶35.

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[3] This is not a case where the term turns "on a person's tastes or opinion." *See Sonix*, 844 F.3d at 1378. Unlike the terms "aesthetically pleasing" and "in an unobtrusive manner that does not distract," "rough particulate matter" is subject to an objective standard.

Rebiotix next contends that "non-fecal floral material" "creates [ ] confusion" because it can include bacteria. Answer at 16. Not so. The claims and specification make clear that "rough particulate matter" constitutes non-living matter, as distinguished from the bacterial composition of stool. *See, e.g.*, '309 patent claim 1; 7:42 ("the fecal flora is separated from rough particulate matter"). Rebiotix's expert admitted that non-fecal floral matter is not bacteria. Ex. 66 at 73:9-11. There is nothing subjective about what is and is not living matter.

The variations of "non-fecal floral material" also do not render the claims indefinite. *Contra* Answer at 16-17. Patentees may "use[ ] different words to express similar concepts." *See, e.g.*, *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1120 (Fed. Cir. 2004).[4] The bacteria in stool may be referred to as "floral matter" or more specifically, "fecal floral matter." The converse of both terms—"non-floral matter" and "non-fecal floral matter"— refers to matter that is not the bacteria. Other variations of the term are no less clear. And critically, regardless of which of those terms is used for purposes of this construction, the specification repeatedly confirms that rough particulate matter is distinct from the matter that remains after its removal; *i.e.,* the microscopic non-living matter and bacteria. *See, e.g.*, '309 patent at 21:18-25. That is an undisputable quality of rough particulate matter, and the Court's construction should reflect it.

Finally, the parties agree: the Examiner considered the term "free of rough particulate matter" and determined it was definite.[5] *See, e.g.*, Ex. 38 at JA0621. Answer at 17.

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[4] Contrary to Rebiotix's suggestion, Answer at 17, there is no need to rewrite the claims. The term "non-fecal floral material" is not before the Court for construction. Rather, "non-fecal floral material" is part of the definition of "rough particulate matter."

[5] Following service of Finch's Opening Position, the Federal Circuit modified its opinion in *Nature Simulation*, a case cited by Finch, deleting the language quoted above. *Nature*

4. Plaintiffs' sur-reply position

Counterclaimants' shifting interpretations of their proposed construction of "rough particulate matter" confirm the term is indefinite. Specifically, in reply, Counterclaimants now assert that "irregular" is based on the composition as a whole, while "macroscopic" is a property of the particle, and they assert a meaning for "non-fecal floral material" that is the exact opposite of what the words mean.

With respect to "irregular," Counterclaimants originally asserted that "irregular" was a property of the particles themselves. (*Supra* at 12 ("[T]here is also no question that 'rough' particles are 'irregular' in shape, as proposed by Finch's construction.").) In response, Plaintiffs and Dr. Johnson explained how "irregular" excludes particles (such as corn and smooth beans) that both parties' experts agree are rough particulate matter. (*Supra* at 15; Johnson Decl. ¶ 36; Allegretti Decl. ¶ 39; Ex. 67 at 75:1-76:5.). Recognizing this, Counterclaimants argue in reply that "rough particulate matter consists of non-uniform particles, which are distinct from the uniform composition that remains after homogenization, centrifugation, or filtering." (*Supra* at 19.) Dr. Allegretti confirmed this, stating that "rough particulate matter is 'irregular' with respect to the consistency of the composition as a whole, not the shape of a single particle." (Allegretti Decl. ¶ 38.)

With respect to "macroscopic," however, Counterclaimants and Dr. Allegretti assert that "whether a particle is macroscopic is an objective property of the particle." (*See* Allegretti Decl. ¶ 40; Ex. 67 at 75:25-76:5; *see also supra* at 18 ("'[M]acroscopic' is an objective standard.").)

Simulation Sys. Inc. v. Autodesk, Inc., 50 F.4th 1358 (Fed. Cir. 2022). However, the Federal Circuit did not overturn its initial finding, nor did it disrupt the finding in *Tinnus*, the case initially quoted by the Court in *Nature Simulation*.

Further, despite Counterclaimants arguments, and unlike *Sonix*, the Borody specification provides no detail about what is, and is not, "macroscopic" and does not even use the term. *Compare* Ex. 1 *with Sonix*, 844 F.3d at 1378. In support of the objective standard, Dr. Allegretti argued that "macroscopic" is not whether a POSA "can" see the particle, just whether a POSA could be "capable" of seeing the particle. (Ex. 67 at 81:22-82:1.) But "capable" necessarily requires determining a set of conditions, making the term subjective. Tellingly, Dr. Allegretti would not admit that a particle capable of being seen under one set of conditions—but not under another—is macroscopic, (Ex. 67 at 82:2-12), stating instead she would need to see it first (Ex. 67 at 80:13-81:13).

To add to the ambiguity, the "non-fecal floral material" portion of Counterclaimants' construction is non-sensical. The phrase means floral material that is non-fecal, i.e., microorganisms (including bacteria) not from the feces. (*See supra* at 16-17.) But Counterclaimants misconstrue the plain meaning of the term, asserting that "non-floral matter" and "non-fecal floral matter" mean the same thing—"not the bacteria." (*Supra* at 20.) Not so. The first means matter that is not the microorganisms, and the second means "microorganisms not from the feces." Similarly, Dr. Allegretti morphs "non-fecal floral material" (Allegretti Decl. ¶ 27) into "non-living or non-fecal floral material" (*id.* ¶ 29), and then "non-living material" (*id.* ¶ 34); and then further testified that "floral material" is not limited to just bacteria (as Counterclaimants assert). (*See, e.g.*, Ex. 67 at 60:22-61:3; 63:11-13.) However, Dr. Allegretti admitted that the word non-fecal means "not from the feces" (*id.* at 57:22-25) and that "irregular," "macroscopic," "non-fecal," and "floral" are all adjectives modifying "material" (*id.* at 55:10-558:19; 63:9-21). Thus, Counterclaimants' proposed definition means "rough particulate matter" is "irregular, macroscopic living microorganisms (such as, but not limited to,

bacteria) that are not from the feces." And as Plaintiffs previously explained, Counterclaimants' (and now Dr. Allegretti's) citation to other terms in the Borody specification is unavailing. (*Supra* at 16-17.) These words—"non-fecal floral fecal material" and "non-floral matter of the fecal material"—are not the same as "non-fecal floral material." Even Dr. Allegretti admitted that "non-fecal floral fecal material," used to describe multiple "aspects" of the invention (*see* Ex. 1 at 2:65-6:17), refers to material that is simultaneously both from, and not from, the feces (Ex. 67 at 64:16-65:7).

Accordingly, the term "rough particulate matter," and Counterclaimants' definition thereof, are indefinite because they fail to inform a POSA with reasonable certainty about the scope of the claimed subject matter.

B. "free of" / "free of rough particulate matter"

Claims	Term	Plaintiffs' Proposed Construction	Finch's Proposed Construction
'406 patent: claim 4 '702 patent: claims 1, 13 '309 patent: claim 1	"free of"	"a zero amount," otherwise indefinite	"less than 1%"
'406 patent: claim 4 '702 patent: claims 1, 13 '309 patent: claim 1	"free of rough particulate matter"	"a zero amount of rough particulate matter," otherwise indefinite	"less than 1% of irregular, macroscopic non-fecal floral matter"

1. Finch's opening position

This dispute—which is the primary dispute underlying the terms in this section and in the following section, Part IV.C.—focuses on how much rough particulate matter remains in the patented composition after it is processed in the donor stool sample: either (1) less than 1% of the composition (Finch's proposal) or (2) none (Rebiotix's proposal). Rebiotix is incorrect—as discussed below, Rebiotix's construction would improperly exclude embodiments that explicitly confirm Finch's construction.

The specification repeatedly states that the separation or removal of rough particulate matter need not be perfect, and that some amount of residual rough particulate matter may remain in the claimed compositions. According to the specification, a "purified fecal flora" still includes up to 1% non fecal-floral material:

> the delivery vehicle, formulation, pharmaceutical preparation, product of manufacture, container or device of any of (a) to (j), wherein a substantially isolated or a purified fecal flora or entire (or substantially entire) microbiota is (comprises) an isolate of fecal flora that is at least about 90%, 91%, 92%, 93%, 94%, 95%, 96%, 97%, 98%, 99%, 99.5%, 99.6%, 99.7%, 99.8% or 99.9% isolated or

> pure, or having no more than about 0.1%, 0.2%, 0.3%, 0.4%, 0.5%, 0.6%, 0.7%, 0.8%, 0.9% or 1.0% or more non-fecal floral material;

'309 patent at 7:64-8:6; 10:21-28 (same), 13:32-40 (same). This "1% or more non-fecal floral material" can include rough particulate matter; indeed, in some embodiments, the only non-fecal floral material that is separated from the donor stool sample is the rough particulate matter. *See, e.g.*, '309 patent at 21:20-23; (". . . the stool can be homogenized and filtered from rough particulate matter. In alternative embodiments, the microscopic fiber/nonliving matter is then separated from the bacteria."); *compare* '107 patent, claim 11 ("wherein the filtering separates bacteria from microscopic fiber") *with* '107 patent, claim 12 ("wherein the filtering separates bacteria from rough particulate matter"). As a result, as confirmed by the specification, even the "highest concentration" of bacteria is "almost 100%" but not actually 100% bacteria—it still includes non-fecal floral matter, such as rough particulate matter. '309 patent at 21:32-34 ("In one embodiment, a filtration procedure for filtering whole stool is suitably used to reach the highest concentration of almost 100% bacteria."). The contemplation of a "purified" flora that allows for up to 1% non-fecal floral matter (such as rough particulate matter) reflects the patentee's recognition that the invention can achieve its goals even when some rough particulate matter remains, and that it may not be realistic to achieve complete removal.

The specification further confirms that being "free" of a certain material does not mean "100% free." For example, when describing an "oxygen free" composition, the specification allows for up to 10% oxygen, and never refers to "100%" free. *See* '309 patent at 6:57-62 ("(a), wherein the delivery vehicle, formulation, pharmaceutical preparation, product of manufacture, container or device is made substantially or completely oxygen free (e.g., at least about 90% . . . or 99.9% oxygen free)").

Rebiotix's construction, by contrast, is improper, as it would exclude nearly every embodiment in the specification—a result that is rarely, if ever correct. *See Wasica Fin. GmbH v. Cont'l Auto. Sys., Inc.*, 853 F.3d 1272, 1282 (Fed. Cir. 2017) ("We normally do not interpret claim terms in a way that excludes disclosed examples in the specification"). And while the specification leaves open the possibility of having "zero" rough particulate matter in the patented composition (stating that it may have "no more than" 1.0% "or more" non-fecal floral material ('309 patent at 7:64-8:6; 10:21-28, 13:32-40), it does not explicitly disclose such an embodiment, and even if it did, there is no basis to limit the claims to just that one potential embodiment. *Epos Techs. Ltd. v. Pegasus Techs. Ltd.*, 766 F.3d 1338, 1341 (Fed. Cir. 2014) ("it is improper to read limitations from a preferred embodiment described in the specification—even if it is the only embodiment—into the claims absent a clear indication in the intrinsic record that the patentee intended the claims to be so limited") (quoting *Liebel–Flarsheim v. Medrad, Inc.*, 358 F.3d 898, 913 (Fed. Cir. 2004)).

Rebiotix's fallback—seeking a determination of indefiniteness—is unavailing. Finch's construction is well-supported by repeated references to how much rough particulate matter can remain after separation (*i.e.,* up to 1%)—that is clearly definite. Moreover, this phrase was specifically considered by the Examiner and determined to be definite. *See* Ex. 38 at JA0621.[6] As discussed in Part IV.A., that precludes a finding that Rebiotix has established indefiniteness by clear and convincing evidence. *Nature Simulation*, 23 F.4th at 1342-43.

[6] The same reasoning applies to similar amendments made during prosecution of other applications in this family. *See, e.g.*, Ex. 24 at JA0472.

2. Plaintiffs' answering position

The intrinsic evidence dictates that the term "free of" means "a zero amount"; otherwise, the term is indefinite. Counterclaimants' argument for their proposed construction of "less than 1%" ignores the prosecution history, which makes clear that the applicant chose to claim "free of rough particulate matter" to overcome indefiniteness rejections of the terms "substantially devoid of fiber" and "substantially free of non-living matter."

The prosecution history is dispositive here. During prosecution of the '406 patent (from which all of the other Borody patents flow as continuations), the applicant presented claim 44 that contained the term "substantially devoid of fiber" and claim 47 that contained the term "substantially free of non-living matter." (Ex. 19 at JA0400.) In rejecting pending claims 44 and 47 as indefinite, the Examiner stated:

> The phrase "substantially devoid of fiber" in claim 44 renders the claim indefinite. While "substantially entire microbiota" is properly defined in the Specification (page 9), the relative term "substantially" in said phrase is not defined by the claim, the specification does not provide a standard for assessing the requisite degree, and one of ordinary skill in the art would not reasonably be apprised of the scope of the invention. For example, does the phrase "substantially devoid of fiber" allow the composition to have 10% or less fiber in the composition? Or does it require the composition to comprise no more than about 1% fiber? In the interest of compact prosecution, the latter interpretation is taken.
>
> Similarly, the recitation "substantially free of non-living matter" renders claim 47 indefinite because it is not properly defined by the disclosure. Based on the description on the amount of non-fecal floral material in the Specification (page 9), this recitation is interpreted to mean that the composition has no more than about 1.0% of non-living matter for the purpose of applying prior art.

(Ex. 20 at JA0413-14; *see also* Ex. 22 at JA0449 (maintaining the rejections).)

In response to the indefiniteness rejection, the applicant cancelled claims 44 and 47 and amended then pending claim 70 to recite, "A filtered and homogenized stool composition comprising the substantially entire microbiota of a stool and an added antioxidant, wherein said stool composition is **free of rough particulate matter** of said stool." (Ex. 23 at JA0465, JA0469 (emphasis added).) In an Applicant-Initiated Interview Summary that followed, the examiner noted that "[a]mendments that can overcome 112 rejections including indefiniteness over the terms 'substantially devoid of fiber' and 'substantially free of non-living fecal matter' (by replacing it with 'free of rough particulate matter of said stool' instead) . . . were discussed." (Ex. 24 at JA0472.) The examiner subsequently allowed claim 70 (now asserted claim 4 of the '406 patent). In the Notice of Allowance, the examiner stated, "[t]he invention is directed to a composition comprising stool bacteria or microbiota without fiber or stool rough particulate matter." (Ex. 25 at JA0479.)

Counterclaimants' proposed construction of "less than 1%" improperly attempts to equate "free of" with "substantially devoid" or "substantially free of"—terms that, as discussed above, were rejected as indefinite during prosecution. That is, Counterclaimant's proposed construction of "less than 1%" is tantamount to the "substantially devoid" and "substantially free of" terms rejected as indefinite by the examiner. (*See* Ex. 22 at JA0449.) In contrast, Plaintiffs' proposed construction of "a zero amount" is consistent with the examiner's description of the invention (Ex. 25 at JA0479), as well as the specification.

Ignoring the prosecution history, Counterclaimants' primary argument against Plaintiffs' construction is that Plaintiffs' construction would exclude "nearly every" embodiment disclosed in the specification. (*Supra* at 26.) This is incorrect.

First, as Counterclaimants note, the specification provides that (i) "non-fecal floral matter" can include both rough particulate matter and microscopic/non-living fiber, and (ii) the stool can be processed to remove rough particulate matter (i.e., have a zero amount of rough particulate matter), but still contain microscopic/non-living fiber

Specifically, Counterclaimants rely on the same passage of the specification for their construction of "free of" that Plaintiffs point to as the patentee's lexicographer definition of the term "substantially entire microbiota":

> a substantially isolated or a purified fecal flora or entire (or substantially entire) microbiota is (comprises) an isolate of fecal flora that is at least about 90%, 91%, 92%, 93%, 94%, 95%, 96%, 97%, 98%, 99%, 99.5%, 99.6%, 99.7%, 99.8% or 99.9% isolated or pure, or having no more than about 0.1%, 0.2%, 0.3%, 0.4%, 0.5%, 0.6%, 0.7%, 0.8%, 0.9% or 1.0% or more non-fecal floral material.

(*Compare supra* at 24-25 (citing Ex. 1 at 7:64-8:6, 10:21-28, 13:32-40) *with infra* at §IV.D.2.) Specifically, Counterclaimants argue that the recited "1% or more non-fecal floral material" supports construing "free of" rough particulate matter to mean "less than 1%" rough particulate matter. (*Supra* at 24-25.) However, Counterclaimants admit that the "1% or more non-fecal floral material" can include both rough particulate matter as well as microscopic/non-living fiber; indeed, Counterclaimants specifically point to the portion of the specification which states "the stool can be homogenized and filtered from rough particulate matter. In alternative embodiments, the microscopic fiber/nonliving matter is then separated from the bacteria." (*Supra* at 25 (citing Ex. 1 at 21:20-23).)

Counterclaimants then improperly conclude that the specification's disclosure of "a filtration procedure for filtering whole stool is suitably used to reach the highest concentration of almost 100% bacteria" (*supra* at 25 (citing Ex. 1 at 21:32-34)) means that non-fecal floral material must remain, including rough particulate matter (*supra* at 25). However, even if the

highest concentration of the claimed composition is not 100% bacteria, it does not necessarily mean that the composition includes rough particulate matter. It could have zero rough particulate matter, but still contain microscopic fiber (or other non-living matter that is not rough particulate matter). Regardless, Counterclaimants admit the passage they rely on above supports "the possibility of having 'zero' rough particulate matter in the patented composition." (*See supra* at 26 (citing Ex. 1 at 7:64-8:6, 10:21-28, 13:32-40); *see also supra* at 24-25.)

Second, Counterclaimants incorrectly argue that the specification "does not explicitly disclose" an embodiment having zero rough particulate matter. (*Supra* at 26.) However, the specification explicitly states "[i]n one embodiment, these preparations do not contain any (or are substantially [f]ree of) non-floral material, e.g., non-absorbed components normally present in a fecal sample, e.g., a raw human stool." (Ex. 1 at 24:56-60.)

For these reasons, Counterclaimants' argument that Plaintiffs' construction would improperly exclude embodiments should be rejected. *See TIP Sys., LLC v. Phillips & Brooks/Gladwin, Inc.*, 529 F.2d 1364, 1373 (Fed. Cir. 2008) (noting that "the claims of the patent need not encompass all disclosed embodiments" and that Federal Circuit "precedent is replete with examples of subject matter that is included in the specification, but is not claimed"); s*ee also Schoenhaus v. Genesco, Inc.*, 440 F.3d 1354, 1359 (Fed. Cir. 2006) (noting that a patentee "is only entitled to protection of the claims as issued", which can exclude embodiments described in the specification).

3. Finch's reply position

Rebiotix does not dispute that the specification expressly discloses embodiments containing non-living matter, which may include rough particulate matter.[7] *See, e.g.*, '309 patent at 7:64-8:6; 10:21-28, 13:32-40. Rebiotix provides no explanation for its insinuation that such embodiments are at odds with an embodiment containing zero rough particulate matter, nor why such express disclosures in the specification should be ignored. They should not be.

Rebiotix's reliance on the prosecution history is also misplaced. The Federal Circuit has warned that "because the prosecution history represents an ongoing negotiation between the PTO and the Applicant, rather than the final product of that negotiation, it often lacks the clarity of the specification and thus is less useful for claim construction purposes." *Cont'l Cirs. LLC v. Intel Corp.*, 915 F.3d 788, 796 (Fed. Cir. 2019). Just so here. "[S]ubstantially devoid of fiber" and "substantially free of non-living matter" were not replaced with "free of rough particulate matter" during prosecution. Claim 44 ("substantially devoid of fiber") and claim 47 ("substantially free of non-living matter") were both cancelled. Ex. 21 at JA0432; Ex. 23 at JA0465. A different claim (claim 70) was amended to add "wherein said stool composition is free of rough particulate matter of said stool." Ex. 23 at JA0465. This does not meet the high bar of clear and unmistakable disavowal. At most, these are clarifications of claim scope, not disclaimer. *See Kraft Foods Grp. Brands LLC v. TC Heartland, LLC*, No. CV 14-028-LPS, 2016 WL 873435, at *8 (D. Del. Mar. 7, 2016) ("prosecution history shows that the patentee clarified, rather than narrowed, the scope of the claims" following indefiniteness rejection).

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[7] Notably, Rebiotix says "free of" must mean "zero," but contends that "substantially entire microbiota" encompasses up to 1% non-fecal floral material remaining in the composition, which may include rough particulate matter—confirming Finch's construction.

"[W]here, as here, 'the alleged disavowal is ambiguous, or even amenable to multiple reasonable interpretations,'" the Court should decline to find disclaimer. *See Cornell Univ. v. Illumina, Inc.*, No. CV 10-433-LPS-MPT, 2017 WL 89165, at *5 (D. Del. Jan. 10, 2017) (*quoting Avid Tech., Inc. v. Harmonic, Inc*., 812 F.3d 1040, 1045 (Fed. Cir. 2016)).

Rebiotix also points to the Notice of Allowance referencing "a composition comprising stool bacteria or microbiota without fiber or stool rough particulate." Ex. 25 at JA0479. Even if this phrase was intended to cover the patent's embodiments, it is undisputed that the specification includes embodiments that could contain rough particulate matter. The Examiner acknowledged that embodiments may contain "no more than about 1.0% of non-living matter," *see, e.g.*, Ex. 20 at JA0413-414, which, as the specification confirms, may include rough particulate matter. '309 patent at 7:41-45; 9:40-44; 11:61-64. And, "[i]t is well settled" "that it is the applicant, not the examiner, who must give up or disclaim subject matter that would otherwise fall within the scope of the claims." *Innova/Pure Water*, 381 F.3d at 1124.

4. Plaintiffs' sur-reply position

Both parties acknowledge that claim 4 of the '406 patent (claim 70 during prosecution) was amended to add the phrase "wherein said stool composition is free of rough particulate matter of said stool." (*See supra* at 28, 31.) This is not a situation where the applicant was using similar language to "clarify" a claim, as in *Kraft Foods*, 2016 WL 873435, at *8. Specifically, claim 70 was rejected as obvious over Hlavka in part because Hlavka taught blending and filtering. (Ex. 22 at JA0455-56.) The applicant and Examiner specifically discussed overcoming the Hlavka obviousness rejection and why indefiniteness would be obviated by the term "free of rough particulate matter of the stool." (Ex. 24 at JA0472.) With the added language, the Examiner allowed claim 70, noting that "[t]he invention is directed to a composition comprising stool bacteria or microbiota without fiber or stool rough particulate" and that "Hlavka is different

from the claimed composition [in] that fecal samples are not specifically taught to be free of fiber or rough particulate matter of stool." (Ex. 25 at JA0479.)

That "free of" means "without" was further confirmed during the prosecution of a related patent. There, the term "substantially free of fiber" was rejected as indefinite because the phrase was "not defined by the claims nor the specification" and thus it was unclear "[h]ow much fiber is allowed in the mixture such that it is considered substantially free? For example, is <1% fiber in the mixture sufficient." (Ex. 36 at JA0609.) In response, Applicant affirmatively replaced the term with "free of rough particulate matter of the stool sample," (Ex. 37 at JA0612), which was subsequently allowed, (Ex. 38 at JA0621).

C. "the filtering separates bacteria from rough particulate matter" / "separated from rough particulate matter"

Claims	Term	Plaintiffs' Proposed Construction	Finch's Proposed Construction
'107 patent: claims 12, 25	"the filtering separates bacteria from rough particulate matter"	"a zero amount of rough particulate matter achieved by filtration," otherwise indefinite	"the filtering separates bacteria from irregular, macroscopic non-fecal floral material"
'702 patent: claim 11 '309 patent: claim 12	"separated from rough particulate matter"	"a zero amount of rough particulate matter achieved by one or more of homogenizing, filtering, plasmapheresis, centrifugation, celltrifugation, column chromatography, or immunoprecipitation," otherwise indefinite	"separated from irregular, macroscopic non-fecal floral material"

1. Finch's opening position

The "separating" phrases in this group present two primary disputes: (1) a replay of Rebiotix's argument that there may not be more than "zero" rough particulate matter remaining in the patented composition after it is separated from the donor stool sample; and (2) whether exemplary "separation" processes set forth in the specification should be written into the claims (Finch asserts that they should not; Rebiotix contends that they should). Rebiotix is incorrect on both points.

With respect to how much rough particulate matter may remain after separation, as discussed in Part IV.B., it is more than zero, as confirmed throughout the specification. *See* Part IV.B. above. Once again, Rebiotix's proposed construction improperly excludes numerous embodiments that are described throughout the specification, and attempts to limit the claims to an embodiment that the specifications do not explicitly discuss. '309 patent at 7:64-8:6, 10:21-

28; *see also id*. at 7:41-45, 9:41-48, 21:18-21, 23:1-6. That is improper (and would be improper even if a "zero" embodiment were explicitly discussed). *Epos*, 766 F.3d at 1341.

Aside from the construction of "rough particulate matter" discussed above, no further construction is necessary, as a POSA would readily understand the meaning of "the filtering separates" and "separated from." In particular, "[s]eparated from" does not require any specific process of separation. The exemplary "separation" processes set forth in the specification should not be written into the claims. *Epos*, 766 F.3d at 1341. "Exemplary language, without more, does not constitute a disclaimer." *Data Engine Techs. LLC v. Google Inc*., No. CV 14-1115-LPS, 2016 WL 790957, at *6 (D. Del. Feb. 29, 2016). Here, Rebiotix has failed to identify any portion of the specification requiring that the invention must use one or more of the processes named in Rebiotix's proposed construction or that the invention cannot be practiced with alternative means. Such limitations should not be injected into the claims through their construction.

Once again, Rebiotix's fallback indefiniteness argument should be rejected. Finch's construction is well-supported by the specification's numerous examples. '309 patent at 7:41-45, 7:64-8:6, 9:41-48, 10:21-28, 21:18-21; 23:1-6; *see, e.g.*, *PPS Data, LLC v. Jack Henry & Assocs., Inc.*, No. 2:18-CV-00007-JRG, 2019 WL 1040742, at *21 (E.D. Tex. Mar. 4, 2019) ("Defendant has not shown that the claims or the specification attribute any special meaning to the word 'separate' or that the precise degree of separation has any special significance. The Court therefore hereby expressly rejects Defendant's indefiniteness argument, and no further construction is necessary."). These terms can be understood with reasonable certainty.

2. Plaintiffs' answering position

The terms "the filtering separates bacteria from rough particulate matter" and "separated from rough particulate matter" should be construed, respectively, to require "a zero amount of

rough particulate matter achieved by filtration" and "a zero amount of rough particulate matter achieved by one or more of homogenizing, filtering, plasmapheresis, centrifugation, celltrifugation, column chromatography, or immunoprecipitation." Otherwise, the terms are indefinite as they allow for an indeterminate amount of separation. Counterclaimants' proposed constructions, on the other hand, provide no clarity to either term because their proposed constructions simply restate the claim terms while swapping out "rough particulate matter" for their proposed constructions of those terms.

First, the term "separate" has a widely understood meaning which requires a total disassociation between constituent elements. (*See, e.g.*, Ex. 65 at JA0875 (defining separate as "To set or keep apart; disunite" and "To remove from a mixture or combination; isolate"); Ex. 58 at JA0809 (defining separate as ("forming or viewed as a unit apart or by itself," "not joined or touching physically," "cause to move or be apart," "form a distinction or boundary between," and "divide or cause to divide into constituent or distinct elements"); *see also* Ex. 62 at JA0833.) In other words, the plain meaning of the term separate (which Counterclaimants merely repeat in their definition without defining) requires a complete separation.

Second, as described above with respect to the "free of" terms, the intrinsic evidence (by Counterclaimants' own admission) supports construing "separates" and "separated from" to require a zero amount of rough particulate matter. (*See supra* at §IV.B.2.) Allowing for an indeterminate amount of separation would render the claims indefinite because a person of ordinary skill in the art would not know how much separation is necessary. Is it sufficient to remove a single particle of rough particulate matter? Is 10% sufficient? 50%? 90%? 99.9%? Reasonable POSAs may disagree as to the degree of separation necessary, which is the hallmark of indefiniteness. *Media Rts.*, 800 F.3d at 1371.

Third, the intrinsic evidence dictates the types of separation methods that are covered by the claims. There is no dispute that the plain language of claims 12 and 25 of the '107 patent makes clear that the separating method is filtration—"the filtering separates bacteria from rough particulate matter." (Ex. 5 at cls. 12 and 25.) Instead, Counterclaimants assert that Plaintiffs are importing the "exemplary 'separation' processes set forth in the specification" into the claims. (*Supra* at 34.) Not true. The only "separation processes" repeatedly disclosed in the specification are homogenization, filtration, plasmapheresis, centrifugation, celltrifugation, column chromatography, and immunoprecipitation. (*See, e.g.*, Ex. 1 at 7:39-48, 9:40-48, 23:1-7, 23:18-22, 24:43-49.) Further, it is hard to see what additional separation processes would be available to a POSA, and Counterclaimants have failed to point to any process that would have been available to a POSA at the time of the invention (or is available now) that is not encompassed within the processes disclosed by the claims. Thus, Plaintiffs' construction is consistent with the intrinsic evidence and should be adopted.

3. Finch's reply position

Rebiotix agrees that "the term 'separate' has a widely understood meaning," Answer at 36, yet attempts to import embodiments from the specification into the claims. *Id*. at 37. This is improper. The claims do not include such requirements, nor does Rebiotix point to any intrinsic evidence suggesting they must. Even if Rebiotix were correct as to "[t]he only 'separation processes' repeatedly disclosed," Answer at 37, that is not a basis to read those processes into the claims. *See, e.g.*, *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1328 (Fed. Cir. 2002); *SRI Int'l v. Matsushita Elec. Corp. of Am.*, 775 F.2d 1107, 1121 (Fed. Cir. 1985) ("If everything in the specification were required to be read into the claims . . . there would be no need for claims.").

"Separate" does not require "a zero amount." Rebiotix fails to identify any language in the claims or specification requiring that definition. To the contrary, as discussed in Part IV.B, the specification clearly discloses embodiments with some rough particulate matter. These disclosures include compositions "having no more than about 0.1% … or 1.0% or more non-fecal floral material." '309 patent at 7:64-8:6; 10:21-28 (same), 13:32-40 (same). Rebiotix's position also conflicts with the claim language. '702 patent claim 11 recites that the microbiota is "separated from rough particulate matter." Claim 13, which depends directly from claim 11, requires that the microbiota is "free of rough particulate matter." "[T]he presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1314–15 (Fed. Cir. 2005). If Rebiotix's constructions are accepted, claims 11 and 13 would be coextensive. Rebiotix offers nothing to overcome the presumption that this is improper.

None of the dictionary definitions for "separate" offered by Rebiotix recite "total dissociation" or a "zero amount," Answer at 36. These definitions are unsupportive of Rebiotix's construction. Even if they were, they could not be used to conflict with the intrinsic evidence, let alone exclude embodiments allowing for more than a "zero amount" of rough particulate matter. *Vanderlande Indus. Nederland BV v. Int'l Trade Comm'n.*, 366 F.3d 1311, 1322 (Fed. Cir. 2004).

Rebiotix's attempt to cross-reference its arguments on "free of" is likewise unavailing: not only is the prosecution history unsupportive of Rebiotix's position (as explained in Part IV.B.3), it involved different claim language and has no application to the construction of "separates." Ex. 21 at JA0432; Ex. 23 at JA0465.

Lastly, Rebiotix's argument that the claim language is indefinite should be rejected. Rebiotix contends that without its construction, the claims "allow for an indeterminate amount of separation." Answer at 36. But there is no ambiguity as to when components are separated. For example, where filtration is used, once the mixture is passed through the filter, the separation is complete—one portion remains in the sieve, while the other passes through. *See, e.g.*, '309 patent at 21:18-21 ("…to separate the non-bacterial components . . . the stool can be homogenized and filtered from rough particulate matter…"); 30:15-20 ("… the [fecal] sample is prepared (extracted) with saline and filtered."); *see also Enzo Biochem*, 599 F.3d at 1335. There is no "indeterminate" middle ground.

4. Plaintiffs' sur-reply position

If, as Counterclaimants contend, the "separating" terms do not require a "zero amount" (*supra* at 38), Plaintiffs contend the terms require some quantification or they are indefinite. In reply, Counterclaimants point to what they say are "clearly disclos[ed] embodiments" allowing for up to 1% rough particulate matter. (*Id.*) Plaintiffs submit adopting this construction—separating to 1% or less rough particulate matter—would still be consistent with the specification (as argued by Counterclaimants), finds support in the Examiner's interpretation of the "substantially free of" or "substantially devoid" claims discussed by the parties above in Sections IV.A.2, IV.B.2, and IV.B.3, and differentiates between separated from and "free of" (which, when properly construed, requires a zero amount).

D. "substantially entire microbiota"

Term	Plaintiffs' Proposed Construction	Finch's Proposed Construction
'406 patent: claim 4 '413 patent: claims 1, 17 '702 patent: claims 1, 11, 14	"an isolate of fecal flora that is at least about 90%, 91%, 92%, 93%, 94%, 95%, 96%, 97%, 98%, 99%, 99.5%, 99.6%, 99.7%, 99.8%, 99.9% isolated or pure, or having no more than 0.1%, 0.2%, 0.3%, 0.4%, 0.5%, 0.6%, 0.7%, 0.8%, 0.9%, or 1.0% or more non-fecal floral material"	plain and ordinary meaning

1. Finch's opening position

The term "substantially entire microbiota" should receive its plain and ordinary meaning—a result that is consistent with both the intrinsic evidence and numerous authorities construing similar phrases. Rebiotix's construction—which attempts to introduce an unrelated embodiment—should be rejected.

First, no further construction is necessary for the phrase "substantially entire microbiota," as that phrase has a well-understood plain and ordinary meaning. *See, e.g.*, *ADCO Prods., Inc. v. Carlisle Syntec Inc.*, 110 F. Supp. 2d 276, 286 (D. Del. 2000) (citing *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243 (Fed. Cir. 1998) and determining "substantially equal amounts" was "sufficiently clear that no additional construction is necessary."); *York Prods., Inc. v. Cent. Tractor Farm & Fam. Ctr.,* 99 F.3d 1568, 1572-73 (Fed. Cir. 1996) (finding the district court correctly construed the term "a substantial part of the entire height thereof" to mean that "the ridges must cover nearly the entire length of the sidewall"); *Flexi-Mat Corp. v. Dallas Mfg. Co.*, No. CIV.A. 04-10162-DPW, 2006 WL 962161, at *9 (D. Mass. Apr. 11, 2006) (finding that "expressly quantifying a percentage … is unnecessary" and construing "substantially all" to mean "largely, but not wholly"). This phrase does not include technical words beyond the

experience of a lay person, and as such, no further construction is necessary. *ID Image Sensing LLC v. OmniVision Techs., Inc.*, No. CV 20-136-RGA, 2021 WL 5206262, at *3 (D. Del. Nov. 9, 2021) ("[T]he plain and ordinary meaning . . . as always, [is] the default in claim construction.").

Second, Rebiotix's attempt to import into the claims an aspect of the preferred embodiments is improper. As an initial matter, a portion of the passage from the specification that Rebiotix inserts into its construction—referencing the percentage of non-fecal floral material remaining in the patented composition—is unrelated to the "substantially entire microbiota," which refers to the percentage of fecal flora remaining in the patented composition. *Compare* '309 patent at 8:3-5 ("having no more than 0.1% . . . or 1.0% or more non-fecal floral material") *with id.* at 8:1-3 ("an isolate of fecal flora that is at least about 90% . . . or 99.9% isolated"). But to the extent that passage does relate to the "substantially entire microbiota" term at issue, it would still be improper to include it, as it would import an embodiment into the claims.[8] *Epos,* 766 F.3d at 1341; *Data Engine*, 2016 WL 790957, at *6. While it is possible that an embodiment of the claims could cover the percentages set forth in that passage, they are not limited to them.[9] *See, e.g.*, '309 patent at 23:50-55; 23:55-60; 24:50-54. Rebiotix's incorrect attempt to limit the claims should be rejected.

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[8] Tellingly, the phrase "entire (or substantially entire) microbiota" is used no less than 50 times yet only three times do the numerical limitations that Rebiotix improperly imports appear with the term.

[9] And contrary to Rebiotix's implied argument, Rebiotix's construction is not the subject of a definition in the specification.

2. Plaintiffs' answering position

Counterclaimants assert that the term "substantially entire microbiota" should be given its plain and ordinary meaning. Here, the plain and ordinary meaning is inadequate because it fails to define the scope of the disputed term. *O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1361 (Fed. Cir. 2008). This is especially true where, as here, the patentee acted as a lexicographer and defined the term, which counsels against there being a plain and ordinary meaning. *See T-Jat Sys. 2006 Ltd. v. Expedia, Inc.*, No. 16-cv-581-RGA, 2019 WL 3944014 at *6 (D. Del. Aug. 21, 2019) (rejecting the plain and ordinary meaning based on express statements in the specification); *see also Phillips*, 415 F.3d at 1316. Specifically, in three different instances the Finch patents state:

> a substantially isolated or a purified fecal flora or entire (or substantially entire) microbiota is (comprises) an isolate of fecal flora that is at least [sic] about 90%, 91%, 92%, 93%, 945, 95%, 96%, 97%, 98%, 99%, 99.5%, 99.6%, 99.7%, 99.8% or 99.9% isolated or pure, **or** 0.1%, 0.2%, 0.3%, 0.4%, 0.5%, 0.6%, 0.7%, 0.8%, 0.9% or 1.0% or more non-fecal floral material;

(Ex. 1 at 7:64-8:6);

> a substantially isolated or a purified fecal flora is (comprises) an isolate of fecal flora that is at least about 90%, 91%, 92%, 93%, 94%, 95%, 96%, 97%, 98%, 99%, 99.5%, 99.6%, 99.7%, 99.8% or 99.9% isolated or pure, or having no more than about 0.1 %, 0.2%, 0.3%, 0.4%, 0.5%, 0.6%, 0.7%, 0.8%, 0.9% or 1.0% or more non-fecal floral material

(*id.* at 10:21-28);

> a substantially isolated or a purified fecal flora is (comprises) an isolate of the entire (or substantially entire) microbiota or fecal flora that is at least about 90%, 91 %, 92%, 93%, 94%, 95%, 96%, 97%, 98%, 99%, 99.5%, 99.6%, 99.7%, 99.8% or 99.9% isolated or pure, or having no more than about 0.1 %, 0.2%, 0.3%, 0.4%, 0.5%, 0.6%, 0.7%, 0.8%, 0.9% or 1.0% or more non-fecal floral material

(*id.* at 13:32-40). Counterclaimants cite to part of this definition in their argument, (*supra* at 41), but ignore the full statement in context and thus attempt to circumvent its meaning. Counterclaimants argue that, because the term "entire (or substantially entire) microbiota" is used "no less than 50 times" in the specification but the above definition only appears three times, Plaintiffs are importing a limitation from an embodiment into the claims. (*Supra* at 41, n.8.) Not so. While the term "entire (or substantially entire) microbiota" may appear in various places, it is otherwise without context. While not every disclosed embodiment repeats the definition (*see e.g.*, *supra* at 41 (citing Ex. 1 at 23:50-55, 23:55-60, 24:50-54)), the Borody patents provide no other explanation of what the term means other than referring to the numerical limits set forth above. *See T-Jat Sys.*, 2019 WL 3944014, at *6.

Indeed, the examiner responsible for the prosecution of the Borody patents recognized that the applicant acted as a lexicographer. During prosecution of the '406 patent, the applicant presented claim 44 which stated, "A filtered and homogenized stool composition comprising the substantially entire microbiota of a stool and substantially devoid of fiber." (Ex. 19 at JA0400.) In rejecting pending claim 44 as indefinite, the Examiner stated:

> The presence of no more than 0.05% of non-living material present in the fecal sample upon homogenization and filtration reads on the term "substantially entire microbiota" is defined by the Applicant as referring to "at least about 90%, 91% . . . or 99% isolated or pure, or having no more than about 0.1%, 0.2% . . . or 1.0% or more non-fecal floral material."

(Ex. 20 at JA0420.)

Counterclaimants argue, without support, that the portion of Plaintiffs' construction referring to the percentage of non-fecal floral material remaining in the composition ("having no more than about 0.1%, 0.2%, 0.3%, 0.4%, 0.5%, 0.6%, 0.7%, 0.8%, 0.9%, or 1.0% or more non-fecal floral material") is "unrelated to the 'substantially entire microbiota.'" (*Supra* at 41.)

However, as shown above, by its plain language, the patentee's definition is written in the alternative—a fact recognized by the examiner.

Finally, Counterclaimants' citation to cases construing phrases containing the term "substantially" or "substantial" (*supra* at 40-41) are factually distinct. Unlike here, the patentees in those cases did not define "substantial" or "substantially" by numerical limits in the patent specifications. In *ADCO*, the defendant proposed that "substantially equal amounts" should be construed to mean "almost equal with a variation of only a few percentage (i.e., 1-5%)"; however, the court found that the specification provided no support "for imposition of this numerical limit on the claim language." *ADCO,* 110 F. Supp. 2d at 286. Likewise, in *York Products*, the Federal Circuit found that in interpreting the term "a substantial part of the entire height thereof", the specification does "does not provide any indication that the claim terms should be given anything other than their ordinary meaning." *York Prods.,* 99 F.3d at 1573. In *Flexi-Mat*, the parties disputed whether "substantially all" should be expressly quantified, but there was no discussion of whether the specification provided numerical limits. *Flexi-Mat*, 2006 WL 962161, at *8-9.

For the reasons discussed above, the patentee's definition of "substantially entire microbiota" should be adopted.

3. Finch's reply position

Rebiotix's primary argument—that the Applicant expressly defined the term "substantially entire microbiota"—is incorrect. The passages Rebiotix relies on regard a different phrase: "a substantially isolated or a purified fecal flora." Answer at 42-43 (citing '309 patent at 7:64-8:6; 10:21-28; 13:32-40). The difference in language indicates that the Applicant did not intend for the claim language to be limited to that alleged definition. Moreover, those passages do not reflect express definitions, using language like "shall be defined," but rather

appear as elements of some, not all, embodiments. *See GE Lighting Sols., LLC v. AgiLight, Inc.*, 750 F.3d 1304, 1309 (Fed. Cir. 2014).

Rebiotix's reliance on the prosecution history cannot save its construction. Answer at 43. Rebiotix cites no Applicant statements to support its position that the patentee intended to redefine the term. *See, e.g.*, *Innova/Pure Water*, 381 F.3d at 1124 ("it is the Applicant, not the examiner, who must give up or disclaim subject matter"). And, though the Examiner referenced the full paragraph Rebiotix relies on, it is the first portion of the Examiner's definition ("at least about 90%, 91% . . . or 99%") that relates to the microbiota. Rebiotix's inclusion of "having no more than 0.1%, … non-fecal floral material" is therefore, improper, as it refers to the percentage of the resulting composition that is the non-fecal floral material, not the percentage of the microbiota used in the composition. '309 patent at 7:64-8:6; 10:21-28; 13:32-40. Rebiotix fails to reconcile this aspect of the passage with the claim language, other than blindly asserting that it is the Applicant's "definition," Answer at 43-44, confirming that Rebiotix's inclusion of at least that portion in the definition is wrong.

Contrary to Rebiotix's assertions, the term "substantially" does not render the claim indefinite; rather, as shown in Finch's Opening, the term has a well-known plain meaning. Rebiotix attempts to distinguish the cases cited by Finch on the basis that "the patentees in those cases did not define 'substantial' or 'substantially' by numerical limits." Answer at 44. But the "numerical limits" Rebiotix points to at best define a different term. Rebiotix also cites to *O2 Micro* to support its contention that "the plain and ordinary meaning is inadequate." Answer at 42. In *O2 Micro* however, "the parties agreed that 'only if' has a common meaning," but disagreed on when the claimed requirement applied. *O2 Micro*, 521 F.3d at 1361. That is not the case here. Further, Rebiotix cites to this Court's decision in *T-Jat Systems*, suggesting that

this Court "reject[ed] the plain and ordinary meaning based on express statements in the specification." Answer at 42. But there, the court-adopted definition reflected "the plain and ordinary meaning," 2019 WL 3944014 at *6, precisely what Finch proposes here.

4. Plaintiffs' sur-reply position

As discussed in Plaintiffs' answering position, the applicant acted as a lexicographer and expressly defined the term "substantially entire microbiota." (*Supra* at § IV.D.2.) Counterclaimants' reply appears to concede that the portions of the specification define at least the term "a substantially isolated or a purified fecal flora." (*Supra* at 44.) But Counterclaimants' assertion that the passages do not define "substantially entire microbiota" is incorrect. The specification is providing the same definition for any one of four terms: (i) a substantially isolated fecal flora, (ii) a purified fecal flora, (iii) an entire microbiota, or (iv) a substantially entire microbiota. (Ex. 1 at 7:64-8:6.) Indeed, the first cited definition states that "a substantially isolated or a purified fecal flora or entire (or substantially entire) microbiota is (comprises) . . . ." (*Id.*; *see also supra* at 42.) As Counterclaimants argue with respect to other terms, "[p]atentees may 'use[ ] different words to express similar concepts.'" (*Supra* at 20 (quoting *Innova/Pure Water*, 381 F.3d at 1120).) That is the case here.

Further, the prosecution history supports Plaintiffs' contention that the applicant acted as a lexicographer by defining the term. Plaintiffs' citation to the prosecution history merely affirms that the Examiner read the language Plaintiffs point to as a definition. (*Supra* at 43 (quoting Ex. 20 at JA0420).)

Finally, Plaintiffs' briefing does not assert that the claim is indefinite, although Plaintiffs reserve the right to raise indefiniteness depending on the Court's construction.

V. DISPUTED CONSTRUCTIONS IN THE UMN PATENTS

A. "effective amount"

Term	Plaintiffs' Proposed Construction	Finch's Proposed Construction
'011 patent: claim 1 '012 patent: claim 1 '914 patent: claims 1, 4, 9	"a sufficient amount to provide the desired effect (*see, e.g.*, '914 patent at 14:12-33)"	"a sufficient amount to provide the desired effect"

1. Finch's opening position

Both parties agree that "amount effective" in the Borody patents should be construed as "a sufficient amount to provide the desired effect," and to include that language for "effective amount" in the UMN patents. Their agreement is unsurprising: the term (and variations thereof) is ubiquitous in pharmaceutical patents and commonly construed to reflect its ordinary meaning. *See, e.g.*, *Acorda Therapeutics v. Alkem Lab'ys Ltd.*, 2016 Markman 1045356, 2016 WL 1045356, at *3-*4 (D. Del. 2016) ("therapeutically effective blood levels" means "blood levels sufficient to produce a therapeutic effect"); *Immunomedics, Inc. v. Roger Williams Med. Ctr.*, 2017 Markman 788122, 2017 WL 788122, at *5-*7 (D.N.J. 2017) ("effective amount" means "an amount capable of producing the claimed result"); *see also Abbott Lab'ys v. Baxter Pharm. Prods., Inc.*, 334 F.3d 1274, 1277 (Fed. Cir. 2003) ("At the outset, this court notes that the term 'effective amount' has a customary usage."). "Effective amount" in the UMN patents is entirely consistent with this ubiquitous practice: they describe specific, therapeutically beneficial changes in the microbiota of patients suffering from recurring *C. difficile* infection and recite an "effective amount" to do so. *See, e.g.*, '914 patent at 5:44-46; 14:12-20.

The only disagreement is that Rebiotix insists a parenthetical with an exemplary citation to the specification should be included for the UMN patents but not the Borody patents. An

exemplary citation is neither necessary nor proper, not least because the cited passage describes examples of "desired effects" in "some embodiments." '914 patent at 14:12-33. Claims generally should not be limited to examples in the specification. *Epos,* 766 F.3d at 1341 ("it is improper to read limitations from a preferred embodiment described in the specification—even if it is the only embodiment—into the claims absent a clear indication in the intrinsic record that the patentee intended the claims to be so limited") (quoting *Liebel–Flarsheim*, 358 F.3d at 913). To the extent Rebiotix intends its exemplary citation to suggest a narrower meaning than encompassed by the agreed upon portion of the parties' construction, it is incorrect.

Moreover, Rebiotix's proposed addition is entirely unnecessary, especially because the claims themselves explicitly recite the "desired effect" referenced in the agreed upon portion of the parties' constructions. *See Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996) ("First, we look to the words of the claims themselves, both asserted and nonasserted, to define the scope of the patented invention."). For instance, claim 1 of the '914 patent recites "[a] method of decreasing the relative abundance of one or more members of the phylum Proteobacteria in a patient in need thereof … wherein the relative abundance of one or more members of the phylum Proteobacteria is reduced by at least 10% following administration of said pharmaceutical composition." '914 patent at claim 1.

2. Plaintiffs' answering position

As Counterclaimants acknowledge, "[t]he only disagreement [between the parties] is that [Plaintiffs] insist[] a parenthetical with an exemplary citation to the specification should be included for the UMN patents but not the Borody patents." (*Supra* at 47.)

First, the agreed-upon construction for "amount effective" in the Borody patents is irrelevant to the construction of "effective amount" in the UMN patents. The two patent families are unrelated and have different inventors, different specifications, and different claims.

Second, the parenthetical referred to in Plaintiffs' construction is not "exemplary," as Counterclaimants suggest, but constitutes applicants' lexicography for the term "effective amount" and provides context for the lexicographer definition. Specifically, the UMN specification provides:

> As used herein, an "effective amount" relates to a sufficient amount of a composition described herein, to provide the desired effect. For instance, in one embodiment an "effective amount" is an amount effective to alleviate one or more symptoms and/or signs of the disease as described herein. In some embodiments, an effective amount is an amount that is sufficient to effect a reduction in a symptom and/or sign associated with a disease, such as diarrhea or *C. difficile*. A reduction in a symptom and/or a sign is, for instance, at least 10%, at least 20%, at least 30%, at least 40%, at least 50%, at least 60%, at least 70%, at least 80%, at least 90%, or at least 100% in a measured sign as compared to a control, a non-treated subject, or the subject prior to administration of the composition. In one embodiment, an effective amount is an amount sufficient to result in at least $1x10^{10}$ cells, at least $3x10^{10}$ cells, or at least $5x10^{10}$ cells delivered to the colon. It will be understood, however, that the total dosage of the compositions as disclosed herein will be decided by the attending physician within the scope of sound medical judgment. The exact amount required will vary depending on factors such as the type and extent of disease being treated.

(Ex. 2 at 14:12-33.) Thus, the language that follows "effective amount" provides the complete definition of this term.

Third, Counterclaimants' assertion that the term "is ubiquitous in pharmaceutical patents and commonly construed to reflect its ordinary meaning" is misleading at best. (*Supra* at 47.) The cases that Counterclaimants cite all vouch for plain and ordinary meaning or argue that the construction opposed ignores the teachings in the specification. (*Id.*) Counterclaimants here are not arguing the term be given its plain and ordinary meaning, presumably because they acknowledge that the applicants acted as lexicographers.

During the prosecution of the '914 patent, the applicants argued, in response to an indefiniteness challenge, that "Applicant's Specification provides that 'effective amount' is an amount effective to alleviate one or more symptoms and/or signs of the disease as described herein. In some embodiments, an effective amount is an amount that is sufficient to effect a reduction in a symptom and/or sign associated with a disease such as diarrhea or *C. difficile*." (Ex. 13 at JA0311.) In support for their contention that the term "effective amount" was not indefinite, applicants cited to the very language that Plaintiffs now reference in their proposed definition of the term. Importantly, the language applicants quote from the specification for the examiner is ignored by Counterclaimants' construction but acknowledged by Plaintiffs' parenthetical. (Ex. 1 at 14:14-20.) Therefore, the prosecution history supports a broader interpretation of this claim term to include the induced microbiotic changes as well as a reduction in diarrhea or *C. difficile*.

Accordingly, the Court should adopt Plaintiffs' construction.

3. Finch's reply position

Rebiotix's attempt to justify its proposal—adding a "*see, e.g.*" parenthetical to the agreed-upon definition of "effective amount"—should be rejected. Rebiotix insists that the UMN patents include a "lexicographer definition" of the ubiquitous phrase that includes not only the definition the parties agree applies to the Borody patents, but also a number of examples clearly delineated as such with the phrases "[f]or instance" and "[i]n some embodiments." While the first sentence cited by Rebiotix explains what "effective amount" means, none of the following sentences meet the "exacting" standard of lexicography. *GE*, 750 F.3d at 1309.[10]

[10] Rebiotix's reliance on the prosecution history suffers from the same flaw. In referencing the specification, the Applicants expressly stated that these are exemplary teachings, using the

Rebiotix's contention that these exemplary embodiments constitute a definition is contradicted by Rebiotix's construction itself, which uses "*see, e.g.*" in reference thereof. That explicitly indicates there are other exemplary embodiments that are covered by the construction, confirming that these examples are not a definition that should be read into the claims. The law is clear that exemplary embodiments should not be read into the claims. *Epos*, 766 F.3d at 1341. Tellingly, Rebiotix's proposed definition appears to acknowledge as much, only reciting the first sentence cited in the parenthetical, which the parties agree constitutes the meaning of "effective amount," and excluding the remainder of the cited paragraph.[11]

4. Plaintiffs' sur-reply position

The construction of "amount effective" in the Borody patents is at best extrinsic evidence to the meaning of "effective amount" in the UMN patents. *See Shopify Inc. v. Express Mobile, Inc.*, No. 19-439-RGA, 2021 WL 4288113, at *27 n.19 (D. Del. Sept. 21, 2021) (noting that a different patent family was extrinsic evidence in the context of indefiniteness). It is irrelevant if the term "effective amount" has a "ubiquitous" meaning in other patents, (*supra* at 50), because here, the patentees acted as their own lexicographers and defined the term in a paragraph of text (*supra* at 49 (quoting Ex. 2 at 14:12-33)). *Biogen Idec, Inc. v. GlaxoSmithKline LLC*, 713 F.3d 1090, 1097 (Fed. Cir. 2013) (noting that "as used herein" language was definitional). The

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phrases "[f]or example" and "[i]n some embodiments," not that those examples should be required by the claims. *See* Ex. 13 at JA0311.

[11] "[A] sufficient amount to provide the desired effect" is the plain and ordinary meaning of "effective amount," as confirmed by Rebiotix's agreement that "amount effective" in the Borody patents likewise means "a sufficient amount to provide the desired effect." Rebiotix's lexicographer argument provides no basis to deviate from the plain meaning, nor does its proposal to add a "*see, e.g.*" parenthetical to the plain and ordinary meaning serve to change that meaning.

patentees provided a general definition of the term "effective amount," and also specific additional, non-exclusive definitions of the term "effective amount." The paragraph included in Plaintiffs' parenthetical begins with "as used herein" and repeatedly states "an effective amount is." (Ex. 2 at 14:12-33.) This is definitional. *See Biogen Idec*, 713 F.3d at 1097; *see also Astrazeneca AB v. Mutual Pharm. Co.*, 384 F.3d 1333, 1337-38 (Fed. Cir. 2004) (noting that if the patentee "has clearly set forth an explicit definition of the term different from its ordinary meaning," it is binding). Accordingly, Plaintiffs' construction is correct because it includes the complete definition enumerated in the specification.

B. "at least six different classes of bacteria selected from the group consisting of Actinobacteria, Bacteroidia, Bacilli, Clostridia, Erysipelotrichi, Alphaproteobacteria, Betaproteobacteria, Gammaproteobacteria, Mollicutes, and Verrucomicrobiae"

Term	Plaintiffs' Proposed Construction	Finch's Proposed Construction
'011 patent: claim 1 '012 patent: claim 1 '914 patent: claims 1, 4, 9	"selecting at least one bacterial member from at least six of the recited classes," otherwise indefinite	plain and ordinary meaning

1. Finch's opening position

The dispute concerns whether readily understandable claim language—"at least six different classes of bacteria selected from [a] group"—should be reinterpreted to add an active "selecting" step, as Rebiotix proposes. It should not.

The UMN patents describe delivering certain classes of beneficial bacteria obtained from a fecal donor to a patient afflicted with *C. difficile* to achieve a therapeutic effect. The claims describe those bacterial classes using standard "Markush" language to claim multiple elements sharing common characteristics (here, bacterial classes) as a group in a single claim. "A Markush group is a listing of specified alternatives of a group in a patent claim, typically expressed in the form: a member selected from the group consisting of A, B, and C." *Abbott*, 334 F.3d at 1280. Finch's construction recognizes and adopts this standard claiming approach by applying "the default" construction of plain and ordinary meaning to language that needs no construction. *ID Image*, 2021 WL 5206262, at *3.

Rebiotix does not appear to dispute the plain meaning of the various words within the broader phrase: their construction repeats and re-orders many of those words. But Rebiotix nevertheless rewrites the claim language to add an active "selecting" step. To the extent

Rebiotix intends to require purposefully selecting particular bacteria to include in the product, rather than permitting after-the-fact analysis to ensure the classes are present, that requirement is missing from the claim language.[12] Such a requirement would also be inconsistent with the specification, which provides exemplary embodiments in which an active selecting step is not required. *See, e.g.*, '914 patent at 7:37-8:4 (describing "[e]xamples of prokaryotic cells that may be present in a composition of the present invention" and examples "of the present invention" that "may include prokaryotic bacteria" that are members of "at least 6 classes"). Use of "may be present" and "may include" indicates that the bacteria need not have been actively selected for the composition—rather, that claim language merely requires that the requisite diversity of classes be present. *See Wasica*, 853 F.3d at 1282 ("We normally do not interpret claim terms in a way that excludes disclosed examples in the specification").

Yet again, Rebiotix also falls back on indefiniteness, but that argument fails here too. The specification provides exemplary classes of bacteria, detailed explanations of how to determine what bacteria are present in a composition, and specific examples applying such techniques. '914 patent at Figs. 1-3; 6:39-51; 5:19-29. This is more than sufficient. *Lexington Luminance LLC v. Amazon.com Inc.*, 601 F. App'x 963, 968-969 (Fed. Cir. 2015) (holding "that the reasonably ascertainable meaning of the contested claim language is that the substrate must contain one or more of the enumerated members of the claimed group").

2. Plaintiffs' answering position

Plaintiffs submit that this claim requires an active selection step. The intrinsic evidence supports Plaintiffs' construction. The UMN specification provides that the claimed "composition

[12] Notably, other claims within the same patent likewise contain Markush language, but Rebiotix has not sought construction of any of these terms. *See, e.g.*, '914 Patent at claims 5, 13.

includes at least 4 different phyla of gut, colon or intestinal bacteria extracted or prepared from the gut, colon or intestine," such that "the phyla are **chosen** from Bacteroidetes, Firmicutes, Proteobacteria, and Tenericutes." (Ex. 2 at 4:11-18 (emphasis added).) The UMN specification further provides that "[i]n one embodiment, the composition further includes at least 5, 6, 7, 8, 9, or 10 different classes of bacteria **chosen** from Actinobacteria, Bacteroidia, Bacilli, Clostridia, Erysipelotrichi, Alphaproteobacteria, Betaproteobacteria, Gammaproteobacteria, Mollicutes, and Verrucomicrobiae." (Ex. 2 at 5:25-30 (emphasis added).)

Such a requirement does not, as Counterclaimants argue, exclude embodiments disclosed in the specification. First, none of the embodiments cited by Counterclaimants are preferred embodiments and there is a presumption that at least some of the disclosed, non-preferred embodiments are not claimed. *See TIP*, 529 F.2d at 1373–74; s*ee also Schoenhaus*, 440 F.3d at 1359. Further, the paragraph which Counterclaimants cite is nothing more than a laundry list of the types of bacteria that may be present in the preparation, and at most, is a listing of some of the bacteria that were known to exist in the human gut. And as Counterclaimants themselves argued "the UMN scientists developed additional techniques. . . to achieve the right balance of bacterial classes and non-living material" to allegedly improve effectiveness and engraftment. (*Supra* at 1-2.) Actively selecting certain bacteria to ensure their inclusion does not exclude the selection of other bacteria, including the phyla, classes, orders, and families disclosed in column 7. (Ex. 2 at 7:37-62.)

If, as Counterclaimants assert, the term is construed to not require an active selection step, it is indefinite or otherwise invalid. Counterclaimants argue that this phrase is a standard *Markush* group claiming approach and that, as such, only an after-the-fact analysis is required to determine that the claim is met. (*Supra* at 53-54.) To the extent Counterclaimants are correct,

then this limitation is not inventive at least because its active component (the fecal bacteria) is nothing more than a product of nature. Moreover, it is an improper *Markush* group which renders the claim indefinite and invalid. *See* MPEP § 2117 (9th ed. Rev. 10.2019, June 2020) ("A Markush claim contains an 'improper Markush grouping' if either: (1) the members of the Markush group do not share a 'single structural similarity' or (2) the members do not share a common use. *Supplementary Guidelines* at 7166 (citing *In re Harnisch*, 631 F.2d 716, 721-22, 206 USPQ 300, 305 (CCPA 1980))."). The recited classes and plylum(a) do not share structural similarity and common functionality at least because they include known pathogenic bacteria, including *C. difficile*.

Counterclaimants' assertion that the specification of the UMN patents provides "exemplary classes of bacteria, detailed explanations of how to determine what bacteria are present in a composition, and specific examples applying such techniques" (*supra* at 54 (citing Ex. 2 at Figs. 1-3, 6:39-51, and 5:19-29) is incorrect. The only information the UMN patents provide is contained in Example 1 and the corresponding figures, which is for a single patient at certain timepoints and a single donor at a single timepoint. (Ex. 2 at Example 1; 6:39-51.) Indeed, it was not until 2013 (well after the priority date of the UMN patents) that the named inventors published information regarding the sequencing data for the microbiome of three of the forty-three patients and three of the donors described in Example 4. (*See* Ex. 61 at JA0821-23.)

Accordingly, the Court should adopt Plaintiffs' proposed construction of this term.

3. Finch's reply position

Rebiotix confirms its intent to transform standard *Markush* language into an active selection step found nowhere in the claims or required by the intrinsic evidence. Answer at 54 ("Plaintiffs submit that this claim requires an active selection step."). Critically, Rebiotix does not contest that the disputed claim language uses precisely the same phrasing that is typically

used to designate a *Markush* group. *Abbott*, 334 F.3d at 1280 ("A Markush group is … typically expressed in the form: a member selected from the group consisting…"). Instead, Rebiotix argues that if this language is interpreted as claiming a *Markush* group, then the Court should find "this limitation is not inventive," Answer at 55-56, an odd request, to say the least, in the context of claim construction, as "validity arguments are not properly resolved at the claim construction stage." *Forest Lab'ys Inc. v. Cobalt Lab'ys Inc*., No. 08-21-GMS-LPS, 2009 WL 3010837, at *1, n.3 (D. Del. Sept. 21, 2009). Alternatively, Rebiotix invites the Court to find the claim "indefinite and invalid" as a matter of law because, without citing to expert testimony or other evidentiary support, Rebiotix contends that "[t]he recited classes and plylum(a) [sic] do not share structural similarity and common functionality," Answer at 56.[13] Rebiotix's unsupported, and heavily disputed invalidity arguments provide no basis for ignoring the recognized meaning of this standard *Markush* language.[14]

Rebiotix improperly attempts to justify reinterpreting the "selected from the group consisting of" language to require an active selection step, but in the process, selectively excerpts

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[13] Finch disputes Rebiotix's claim as a factual matter. There is no dispute that the named members are all bacteria that may be found in the gut. As confirmed by *In re Harnisch*, "in any Markush group the [members] 'will differ from each other in certain respects.'" 631 F.2d at 722–23 (reversing the Board's rejection based on "improper Markush groups"). The fact that disclosed members may include pathogenic bacteria does not negate the similarities across the group.

[14] To wit, Rebiotix suggests that the data disclosed in Example 1 is insufficient, Answer at 56, but does not explain why data for one patient cannot disclose "exemplary classes of bacteria." Rebiotix also fails to mention that Example 1 comprises nearly two columns, includes details on sequencing analysis used to identify bacterial strains, and cites to three figures disclosing the bacterial strains. '914 patent at 16:1-17:60. The fact that additional data was published later has no bearing on the term's meaning or sufficiency of disclosures. Certainly, Rebiotix has provided no basis for reaching an invalidity determination on this issue at the claim construction stage.

the specification language, tellingly omitting portions of the quoted sentences that make clear that any active selection is optional. For example, Rebiotix states that the specification discloses that the "'composition includes at least 4 different phyla of gut, colon or intestinal bacteria…' such that 'the phyla are chosen from…,'" Answer at 54-55, but the full quote from the specification with the key omitted term underlined actually reads:

> In one embodiment, a composition includes at least 4 different phyla of gut, colon or intestinal bacteria extracted or prepared from the gut, colon or intestine, wherein the phyla include [recitation of phyla], or a combination thereof. Optionally the phyla are chosen from Bacteroidetes, Firmicutes, Proteobacteria, and Tenericutes.

'914 patent at 4:11-18; *id.* at 5:19-24. And the next specification section on which it relies expressly begins with "[i]n one embodiment." Answer at 55. Moreover, Rebiotix suggests that the specification passages Finch identified as referring to the presence of particular bacteria without active selection may be unclaimed embodiments. Answer at 55. But there is no indication in the specification that these embodiments were abandoned by the patentee, and Rebiotix admits that they describe a "list of the types of bacteria that may be present." Answer at 55. The specification does not support Rebiotix's attempt to transform typical *Markush* language into an active selection step.

4. Plaintiffs' sur-reply position

The dispute here is whether this term is a standard *Markush* group (Counterclaimants' position) or whether it requires an active selection step (Plaintiffs' position). If the Court construes this term to require an active selection step, it obviates any subject matter eligibility and indefiniteness arguments regarding the term. *Whittaker Corp. v. UNR Indus., Inc.*, 911 F.2d 709, 712 (Fed. Cir. 1990) ("[C]laims are generally construed so as to sustain their validity, if possible."). Active selection construes the language in a way that is consistent with the specification. (*See supra* § V.B.2.) Determining the term is a *Markush* group raises subject

matter eligibility issues and renders the term indefinite as an improper *Markush* group—the recited classes and phylum(a) contain species with different structures and fulfill different functional roles in the gut, some good, some bad.

C. "extract of feces" / "fecal extract" / "human fecal extract"

Term	Plaintiffs' Proposed Construction	Finch's Proposed Construction
'011 patent: claim 1 '012 patent: claim 1 '914 patent: claims 2, 4, 9	"a composition where the bacteria have been extracted from the unprocessed fecal material and concentrated using conventional sieving and centrifugation steps"	plain and ordinary meaning

1. Finch's opening position

These terms are readily understood, yet Rebiotix proposes a twenty-one word construction that needlessly complicates these two- and three-word phrases and introduces numerous unsupported concepts.

Each disputed phrase refers to an "extract." Rebiotix avoids defining "extract," instead adding two processing steps: both "conventional sieving and centrifugation." This definition lacks intrinsic support, and improperly excludes an embodiment disclosed in the specification, which describes an extract obtained before, and therefore without, centrifugation:

> In one embodiment, the volume of the blended mixture is decreased through the steps of sieving and washing to result in between 1×10^{10} and 5×10^{10} cells in a volume that is subsequently administered to a subject. This process results in an extract of feces that is highly enriched for all colon microbiota…and can be centrifuged at 10,000xg for 10 minutes . . .

'914 patent at 13:2-9. The term's ordinary meaning, as confirmed by the applicant during prosecution, includes no requirement that the extract be obtained before any other processing steps occur. Specifically, the applicant explained that "a person of ordinary skill in the art would understand" the word "extract," pointing to the specification's "use of sieves to extract biological material from fecal material," (Ex. 43 at JA0696-97), and noting that the term's plain meaning in the art:

> "noun 9. something extracted ... 11. a solution or preparation containing the active principles of a drug, plant juice, or the like; concentrated solution: vanilla extract. 12. a solid, viscid, or liquid substance extracted from a plant, drug, or the like, containing its essence in concentrated form: beef extract." *See* http://www.dictionary.com/browse/extract?s=t

Ex. 43 at JA0697. The examiner sought no further amendments to the term.

Numerous dictionary definitions from the time confirm "extract" has a commonly understood definition in the field. *See, e.g.*, Ex. 55, Oxford Dictionary of Biochemistry and Molecular Biology, Revised Edition (2006) ("to obtain a substance from a material, mixture, organism, or part of an organism by some chemical and/or physical process"); Ex. 56, Merriam-Webster's Medical Desk Dictionary (2005) ("to withdraw (as the medically active components of a plant or animal tissue) by physical or chemical process)"). Where, as here, the plain and ordinary meaning of a phrase is "readily apparent," "claim construction …. involves little more than the application of the widely accepted meaning of commonly understood words." *ID Image,* 2021 WL 5206262, at *1 (quoting *Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005)). Rebiotix attempts to unduly narrow this plain meaning in a manner that cannot be reconciled with the intrinsic evidence. For example, claim 9 of the '914 patent recites "administering . . . a pharmaceutical composition comprising a human fecal microbe preparation comprising a pharmaceutically acceptable carrier and a human fecal extract…," which describes a composition that comprises the extract and other elements, yet Rebiotix defines "extract" to be the composition itself.

Finally, the claims do not require bacteria to be extracted from unprocessed fecal material. If Rebiotix intends to argue that the extract must be obtained before any processing occurs, such construction is yet another improper attempt by Rebiotix to unduly narrow the

claims. Because Rebiotix's construction overcomplicates a straightforward term and adds several restrictions that are not supported by the intrinsic evidence, it should be rejected.

2. Plaintiffs' answering position

Contrary to Counterclaimants' position, Plaintiffs' proposed construction of the extract terms does not "needlessly complicate[]" the terms, nor does it "introduce[] numerous unsupported concepts." (*Supra* at 60.) It is clear that the parties dispute the scope and meaning of the extract terms, and as such, it is necessary for the Court to determine its construction now. *O2 Micro*, 521 F.3d at 1361 (finding that the "ordinary" meaning of the disputed term did not resolve the parties' disputes); *see also Howmedica Osteonics Corp. v. Zimmer, Inc.*, 822 F.3d 1312, 1321 (Fed. Cir. 2016) (explaining that "focusing on a particular term's plain and ordinary meaning may be inadequate, when relying on that meaning does not resolve the parties' dispute"); *TQ Delta, LLC. v. Adtran, Inc.*, No. 15-121-RGA, 2019 WL 4917918 at *1 (D. Del. Oct. 4, 2019) (revisiting claim construction when "plain and ordinary meaning" did not resolve the dispute between the parties). Plaintiffs' proposed construction is the only reasonable meaning of the terms based on the specification and prosecution history.

Counterclaimants point to the prosecution of an earlier application as evidence that a POSA would understand the meaning of the extract terms in the context of the claims. The rejection to which applicants were responding was a rejection for indefiniteness. (Ex. 43 at JA0696-97.) Plaintiffs agree the term is not indefinite. The terms have a clear meaning within the context of the UMN patents. That clear meaning is supported by the specification itself and the intrinsic record. And, as Counterclaimants point out, applicants made the meaning of extract clear by citing to dictionary definitions—all of which require concentration. (*Supra* at 60-61 (quoting Ex. 43 at JA0697).)

The UMN specification describes how to prepare the compositions (and the human fecal extract) in several different places—and each requires filtering (sieving is a type of filtering), concentration, and resuspension. For example, the UMN specification provides that the "present invention also provides composition prepared by a process," which "includes subjecting a fecal sample to a condition or conditions that remove at least [a percentage] or more of the non-living material present in the fecal sample." (Ex. 2 at 4:66-5:4.) The UMN specification also teaches various processing embodiments as described in columns 11 to 13. (*See* Ex. 2 at 11:58-13:59.) Each of the embodiments include blending the fecal sample with a diluent, filtering the blended material, concentrating the bacteria, and then resuspending the concentrated extract in a diluent. For example, one embodiment discusses sequential sieving, collection of the filtrate in a centrifuge tube, centrifuging the filtrate "at a speed sufficient to pellet the biological material, for instance, 10,000xg for 10 minutes at 4 ºC," discarding the supernatant and resuspending the extract to make a final preparation. (Ex. 2 at 12:38-64.) The specification also notes that the pellet (which comes from centrifuging) "may be suspended in half the original volume of diluent containing 10% glycerol," or that for cold storage, "the sample may be left in a centrifuge tube." (Ex. 2 at 13:23-28.)

Counterclaimants assert that Plaintiffs' proposed construction would improperly exclude an embodiment disclosed in columns 11 to 13. (*Supra* at 60.) First, the embodiment cited by Counterclaimants is neither an Example nor a preferred embodiment, and as such, there is a presumption that at least some of the disclosed, non-preferred embodiments are not claimed. *See TIP*, 529 F.2d at 1373; s*ee also Schoenhaus*, 440 F.3d at 1359. But Plaintiffs' proposed construction does not exclude the cited embodiment. That embodiment specifically notes that "the volume of the blended mixture is decreased through the steps of sieving and washing." (Ex.

2 at 13:2-9.) As explained by Plaintiffs' expert Dr. Johnson, a washing step for bacteria requires concentration, otherwise, one is simply diluting the suspension with more liquid. (Johnson Decl. at ¶ 43.) This is the exact opposite of what the specification teaches.

The examples from the UMN specification are equally instructive. Example 3 provides the process in total, whereby the fecal sample is to be "passed through a series of four sieves" and "[t]he final filtrate" is to be "collected in 50 ml conical centrifuge tubes and centrifuged at 4,000 rpm (about 4,000xg) for 10 minutes at 4° C." (Ex. 2 at Example 3 (19:38-62).) Next, "[t]he supernatant is discarded" to create a "pellet." (Ex. 2 at 19:57-58.) It is this "pellet" that is the "fecal extract." Example 4 also confirms the requirement of the "conventional sieving and centrifugation steps" necessary to form the "fecal extract." (*See* Ex. 2 at 23:13-58.) This method is also consistent with papers authored by the named inventors and incorporated by reference in their entirety into the specification. (Ex. 2 at 29:4-15, *see, e.g.*, Ex. 63 at JA0837 and Ex. 61 at JA0826 (each cited under "references cited" as "other publications" in the specification (Ex. 2 at JA0039)).) Similarly, it is consistent with patent documents incorporated by reference in their entirety into the specification (Ex. 2 at 29:4-15; Ex. 64 at (noting that "an 'extract' should be taken as excluding a sample taken from the digestive tract in its natural form" and noting that the "extract may be produced by processing such samples, for example to dry and/or enrich the bacteria present in the sample").)

Finally, Counterclaimants remaining arguments are unavailing. There can be no argument that the extract is not a "composition," but Plaintiffs have never suggested that the extract is the same composition as the preparation. It is not. Similarly, as discussed above, the UMN specification consistently describes the process of taking the unprocessed fecal material and creating an extract before reconstitution to form the preparation.

Accordingly, the UMN specification and prosecution history support Plaintiffs' construction that the extract is prepared by filtering and centrifugation.

3. Finch's reply position

Rebiotix struggles mightily to justify its unwieldy re-definition of the straightforward term "extract," which includes a past-tense form of the word itself ("extracted") and adds the requirements that the "extracted" material be "concentrated" using both (i) "sieving" and (ii) "centrifugation."[15] Rebiotix does not appear to dispute that the patents use "extract" consistently with its plain meaning—Rebiotix does not argue that this is an example of lexicography—nor does Rebiotix contest the plain meaning evidence proffered by Finch. Instead, Rebiotix suggests in relatively disorganized fashion that some combination of the specification, dictionary definitions referenced during prosecution, and testimony of its expert somehow justifies its proposal to insert multiple requirements into the "extract" claim terms. Answer at 62-64. No intrinsic or extrinsic evidence comes close to justifying Rebiotix's legally-flawed construction.

Rebiotix insists that "each" description in the specification of "how to prepare the compositions" "requires filtering . . . concentration, and resuspension." Answer at 63; *see also* Johnson Decl. ¶44. Not so. The specification teaches that, "[i]n one embodiment, the volume of the blended mixture is decreased through the steps of sieving and washing … [t]his process results in an extract of feces that . . . can be centrifuged." '914 patent at 13:2-9. This permissive language does not "require" centrifugation at any point, but even if it did, in this embodiment, an extract is formed before any centrifugation has occurred; hence, Rebiotix cannot be right that

[15] To make matters worse, Rebiotix's definition continues to be a moving target, as its expert appears to believe that "extract" also requires washing and homogenization. Ex. 66 at 100:21-24.

every embodiment describing how to obtain an extract requires centrifugation.[16] *See also* '914 patent at 12:56-58 ("The final filtrate may be collected in a centrifuge tube, and centrifuged…"). To the contrary, the specification makes clear that it is filtration, or "use of sieves," that "extract[s] biological material from fecal material." '914 patent at 13:46-47. Indeed, Rebiotix's expert admitted that "[f]iltration steps can extract material." Ex. 66 at 119:20-21. The parties' experts are therefore in agreement that an extract can be obtained with no centrifugation. Allegretti Decl. ¶44.

For support, Rebiotix also cites the "papers authored by the named inventors" and "patent documents" incorporated into the specification by reference. Answer at 64. To the extent these references disclose centrifugation, Rebiotix's reliance on these references goes no further than its identification of embodiments disclosing centrifugation in the specification. However, as with the specification itself, not all embodiments in these references even require centrifugation. *See, e.g.*, Ex. 64 at JA0857-0858 (Example 1B).

But even if every embodiment required centrifugation to obtain an extract, that still would not justify importing a centrifugation requirement into claims that merely require an extract. And, "case law is clear that an applicant is not required to describe in the specification

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[16] To the extent Rebiotix suggests this is an unclaimed embodiment, Answer at 63, this is an implicit admission that it is an embodiment. This description refers to an extract being obtained before centrifugation occurs; Finch's point is that centrifugation is not required by the claims. Regardless, the cases cited by Rebiotix are not relevant here, as they both address circumstances where the specification and claim language are in tension. *See TIP Systems*, 529 F.3d at 1373 ("However, to construe the claim term to encompass the alternative embodiment in this case would contradict the language of the claims."); *Schoenhaus*, 440 F.3d at 1359 ("where a patent specification includes a description lacking a feature, but the claim recites that feature, the language of the claim controls"). There is no tension between the plain meaning of "extract" and the claims.

every conceivable and possible future embodiment of his invention." *Rexnord Corp. v. Laitram Corp.*, 274 F.3d 1336, 1344 (Fed. Cir. 2001) (citing *SRI Int'l v. Matsushita Elec. Corp. of Am.,* 775 F.2d 1107, 1121 (Fed. Cir. 1985)); *see also Innova/Pure Water,* 381 F.3d at 1117. Simply because filtering and centrifugation are process steps disclosed in the specification, they need not, and should not, be read into the claims as defining an extract.

Rebiotix's expert admitted that the basis for his opinion that the "extract" terms require filtration and centrifugation is that this is the only process disclosed in the patent. Ex. 66 at 99:22-100:7. Dr. Johnson is wrong on his understanding of the specification and has not been properly instructed on the law.[17]

Rebiotix also places special import on the word "concentration" as part of its definition. But even if Rebiotix is correct, and an "extract" requires concentration, there can be no dispute that—even if liquid is first added to the stool—the material that has passed through a sieve is concentrated relative to the mass of the original donor stool. Rebiotix's additional language, requiring (1) unprocessed material and (2) centrifugation, is unjustified.

Finally, Rebiotix incorrectly suggests that adopting the plain and ordinary meaning of "extract" would not be proper given the parties' dispute. Answer at 62. Not true. "Plain and ordinary meaning" is the default, and often a proper construction. *ID Image*, 2021 WL 5206262,

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[17] Dr. Johnson also erroneously contends that Finch argued that "'sieving and washing' does not require some method of concentration." Johnson Decl. ¶42. No such argument was made by Finch, but regardless, the question is not whether sieving and washing require concentration, but whether obtaining an extract requires both filtration and centrifugation. It does not. In addition, Rebiotix provides no specific evidentiary support for the "unprocessed" portion of its construction, referring only generally to the specification without any specific cite. Answer at 64. The extrinsic evidence contradicts that aspect of Rebiotix's construction: there is no dispute that it is impractical to extract bacteria from unprocessed stool. Allegretti Decl. ¶44; Ex. 66 at 113:4-114:6.

at *3. None of the cases cited by Rebiotix are inconsistent with adopting plain and ordinary meaning here. This is not the instance where there are multiple plain meanings for the word "extract." *Contra O2 Micro*, 521 F.3d at 1361 ("'plain and ordinary meaning' may be inadequate when a term has more than one 'ordinary' meaning"); *TQ Delta,* 2019 WL 4917918, at *1 (construing "[b]ecause the phrase has multiple plain and ordinary meanings").[18] Rebiotix does not contend that there are multiple plain meanings of "extract," only one of which was claimed; in fact, Rebiotix does not even define the word "extract," repeating the word in its construction. Rather, Rebiotix attempts to mandate multiple process steps for obtaining the extract. There is no support for Rebiotix's construction nor any other reason to depart from the plain and ordinary meaning here.

4. Plaintiffs' sur-reply position

It appears that both parties (and their experts) agree that, at a minimum, creating the human fecal extract requires filtration. Where the parties differ is whether the term also requires concentration. Plaintiffs submit that based on the intrinsic evidence (discussed fully in Plaintiffs' answering position), it does. For example, it is undisputed that during prosecution, the applicants cited to dictionary definitions of the word "extract" to overcome an indefiniteness rejection. (*Supra* at 60-61 (quoting Ex. 43 at JA0696-97); *see also supra* at 62.) And, as Counterclaimants' expert admitted, those definitions require concentration. (Ex. 67 at 96:5-97:10.)

Similarly, the only manufacturing methods discussed in the specification require creating a slurry, filtering it, then concentrating the resulting filtrate—with the only method disclosed for concentration being centrifugation. At a minimum, the intrinsic evidence makes clear that the

[18] *Howmedica* is also inapposite. There, a party only focused "on the specific juxtaposition terms," "ignor[ing] the other claim language at issue." 822 F.3d at 1321.

human fecal extract requires filtration and concentration (even if Counterclaimants are correct and that concentration does not necessarily have to occur by centrifugation). Counterclaimants argue that this concentration will necessarily occur with the filtration step. (*Supra* at 67 ("But even if Rebiotix is correct, and an 'extract' requires concentration, there can be no dispute that—even if liquid is first added to the stool—the material that has passed through a sieve is concentrated relative to the mass of the original donor stool.").) Unfortunately for Counterclaimants, their own expert disputes their assertion. Specifically, Dr. Allegretti indicated that she could not say whether the concentration in the filtrate is higher or lower than the stool sample without testing it, (Ex. 67 at 97:11-98:6), and that it would depend on "several variables." (*id.* at 99:1-12.)

Counterclaimants initially argued that "sieving and washing" was an embodiment that did not require centrifugation. (*Supra* at 60 (quoting Ex. 2 at 13:2-9).) Plaintiffs and Dr. Johnson explained why Counterclaimants were incorrect (*Supra* at 63-64; Johnson Decl. ¶ 43), not least because the embodiment required decreasing the volume of the blended mixture (Ex. 2 at 12:64-13:9). A decrease in the liquid volume of a suspension necessarily increases the concentration of non-liquid material in the suspension. In a footnote, Counterclaimants attempt to skirt the real issue, arguing that they never said "sieving and washing" required concentration. (*Supra* at 67 n.17.) This misses the point; the embodiment specifically discusses decreasing the volume by sieving and washing, which necessarily concentrates the bacteria, and which the UMN specification and Dr. Johnson agree can only be accomplished by filtrating (sieving) and centrifugation (washing). (Ex. 2 at 11:58-13:59, Examples 3, 4; Johnson Decl. ¶¶ 41-44.)

Counterclaimants cite the same example from above to argue that it does not require filtering, concentration, and resuspension. (*Supra* at 65-66.) Counterclaimants appear to concede

that this embodiment (like every other disclosed embodiment) requires filtration but assert that the language indicates that it only "can" be centrifuged. (*Id.*) Incorrect. The embodiment requires sieving and washing to concentrate the product and the cited language requires centrifugation (just like every other disclosed embodiment). What is permissive is the speed and time of the centrifugation. The UMN specification notes that it "can" be at 10,000xg for 10 minutes, but other embodiments and examples are for processed at different speeds for different times. (Ex. 2 at Examples 3, 4.)

D. "human fecal microbe preparation" / "fecal . . . preparation" / "human fecal preparation"

Term	Plaintiffs' Proposed Construction	Finch's Proposed Construction
'011 patent: claim 1 '012 patent: claim 1 '914 patent: claims 1, 4, 9	"a preparation where the human fecal extract has been mixed with at least a diluent for administration"	plain and ordinary meaning

1. Finch's opening position

Though these phrases use readily understood words that require no construction (*e.g.*, "human," "fecal," "preparation"), Rebiotix improperly proposes a seventeen-word construction that simply repeats the term "preparation" and renders understandable claim language needlessly complex, seeking to import a "mixed with at least a diluent" requirement absent from the claim language and other intrinsic evidence.

First, the claim language does not require the preparation to comprise a diluent (or ever mention "diluent"), and where "diluent" is used in the specification, it is consistently referred to in an exemplary manner—there is no *requirement* that a diluent must be added in all cases; in fact, the specification describes the opposite. '914 patent at 10:64 ("For example, they may include diluents…"); 11:58-60 ("[a] composition may be prepared by obtaining a fecal sample…and blending with a diluent"); 11:7-8 ("Oral compositions may include an inert diluent or an edible carrier."). *See, e.g., E-Pass Techs., Inc. v. 3Com Corp.*, 343 F.3d 1364, 1369 (Fed. Cir. 2003) (finding that use of "normally have" in the specification described "a preferred aspect of the invention subject to variability rather than a precise definition"); *Epos*, 766 F.3d at 1341.

Second, Rebiotix seems to require that the claimed composition be made in a stepwise fashion—*i.e.*, the fecal extract is made first, and only then is mixed with something else. This

stepwise requirement is found nowhere in the claims. Even assuming that the "extract" and "preparation" are separately created, the specification explains that "[f]or any method disclosed herein that includes discrete steps, the steps may be conducted in any feasible order. And, as appropriate, any combination of two or more steps may be conducted simultaneously." '914 patent at 6:23-26.

Third, plugging Rebiotix's overly verbose construction into the claims reveals more problems. Adding Rebiotix's construction into claim 9 of the '914 patent results in the following: "[a preparation where the human fecal extract has been mixed with at least a diluent for administration] comprising a pharmaceutically acceptable carrier and a human fecal extract." Rebiotix improperly conflates the separately claimed "human fecal extract" with the "preparation" which comprises it. Moreover, if Rebiotix contends a "diluent" is coextensive with a "pharmaceutically acceptable carrier," its construction of these "preparation" terms would render the "pharmaceuticals acceptable carrier" limitation superfluous. *See, e.g., Digital Ally, Inc. v. Taser Int'l, Inc*., 810 F. App'x 873, 876-77 (Fed. Cir. 2020) (rejecting proposed construction that would render unnecessary a clause of the claim).

2. Plaintiffs' answering position

Counterclaimants again argue that the preparation term has a plain and ordinary meaning and, in doing so, ignore the teachings of the UMN specification. As noted above with respect to the extract terms, the UMN specification consistently describes the process used to make both the human fecal extract and the human fecal microbe preparation. Those steps involve blending the material with a diluent, filtering, concentrating the filtrate through centrifugation to prepare the extract, and then resuspending the extract in a diluent. Plaintiffs' proposed construction is consistent with that disclosure.

First, Plaintiffs note that a diluent is a diluting substance. That is, any substance that is added to the extract to increase weight or volume and that is not part of the extract is a diluent (because it dilutes the extract).

Second, contrary to Counterclaimants' assertion, Plaintiffs' proposed construction neither vitiates the claims nor conflates the preparation with the extract. (*Supra* at 71-72.) It is clear from the structure of the claims that the "human fecal microbe preparation" cannot be coextensive with the "human fecal extract" at least because the "human fecal extract" is a component of the "human fecal microbe preparation." Rather, Plaintiffs' construction recognizes that, by claiming a preparation that comprises an extract, the patentees meant for the terms to have different meaning. *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1119 (Fed. Cir. 2004); *see also UCB, Inc. v. Accord Healthcare, Inc.*, No. 13-cv-1206-LPS, 2015 WL 2345492, at *6 (D. Del. May 14, 2015). That is, the preparation must be a composition that contains something other than just the extract, which is consistent with Plaintiffs' construction.

Third, Plaintiffs do not dispute that the UMN specification allows for combination or reordering of process steps into "any feasible order" "as appropriate." (Ex. 2 at 6:23-26.) Here, the only feasible order is to prepare the extract, then the preparation. The non-living material must be removed and the bacteria must be concentrated to create the extract from which the preparation is then prepared. Attempting to combine making the extract and preparation would not be feasible. (Johnson Decl., ¶ 46.)

Accordingly, the Court should adopt Plaintiffs' construction.

3. Finch's reply position

Rebiotix should be precluded from reading in a limitation that does not exist. It cites no support for the notion that, to achieve a preparation, one must resuspend the extract in a diluent. Answer at 72. Nor does Rebiotix address the specification's express indication that a diluent is

not required in every case, *see, e.g.*, '914 patent at 11:7-8 ("Oral compositions may include an inert diluent"), or explain whether it contends a diluent is coextensive with the "carrier" referenced in the claims, *see, e.g.*, '914 patent, claim 9 ("…human fecal microbe preparation comprising a pharmaceutically acceptable carrier…"). Its silence on these issues speaks volumes, leaving no doubt there is no valid support for its position.

Although Rebiotix acknowledges that the specification allows for reordering the process steps in "any feasible order," it nevertheless asks the Court to determine what is and is not feasible as a matter of claim construction rather than as a factual matter later in the case. Specifically, Rebiotix insists that "the only feasible order is to prepare the extract, then the preparation" and asks the Court to adopt its position as a matter of claim construction. Answer at 73; *see also* Johnson Decl. ¶46. The Federal Circuit has held it improper to impute order into a claim term if "[n]owhere…is there any statement that this order is important, any disclaimer of any other order of steps, or any prosecution history indicating a surrender of any other order of steps." *Altiris, Inc. v. Symantec Corp.*, 318 F.3d 1363, 1371 (Fed. Cir. 2003). So too here. In fact, neither Rebiotix nor Dr. Johnson explain why these steps cannot be performed simultaneously, as explicitly contemplated by the specification. *See* '914 patent at 6:23-26. As Dr. Allegretti explains, the opposite is true: Donor stool can be mixed with another substance to form a solution or slurry, which is then passed through a filter to obtain an extract in solution, that is, a preparation. Allegretti Decl. ¶53. The plain and ordinary meaning of the "preparation" terms captures this embodiment and it would be improper to exclude it, particularly in the context of claim construction.

4. Plaintiffs' sur-reply position

Counterclaimants' argument concerning "diluent" is a red herring. Counterclaimants and Dr. Allegretti admit that in order to process the donor stool, one must mix it with another

substance to form a slurry. (*Supra* at 74 (citing Allegretti Decl. ¶ 53).) Dr. Allegretti opines that "a liquid must be added to the solid stool to form a slurry that can be passed through the pores of a filter." (Allegretti Decl. ¶ 44.) That liquid (or another substance or carrier) is a diluent because it lowers the concentration of the bacteria per unit of measure. The claims require that the preparation contain something other than the extract, and thus the preparation will necessarily contain a diluent.

The dispute here appears to be whether the extract can be made at the same time as the preparation. That question rises and falls with whether the extract requires centrifugation (or at least some form of concentration). As explained in Plaintiffs' answering position, Plaintiffs submit that the UMN specification makes clear that the extract must be made before the preparation. Neither Counterclaimants nor Dr. Allegretti cite to any embodiment or method disclosed in the UMN specification where the preparation is not made subsequent to the extract. Counterclaimants' support amounts to a bald assertion and a citation to a statement that steps may be done in any feasible order or, if feasible, may be combined. (*Supra* at 74 (citing Ex. 1 at 6:23-26 and Allegretti Decl. ¶ 53).) Dr. Johnson has said one cannot make the preparation and extract in a single step if concentration is required, (Johnson Decl. ¶ 46), and, during her deposition, Dr. Allegretti admitted that she had not considered whether one could or not (Ex. 67 at 108:10-17).

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